USER MANUAL

STARRSED INVERSA USER MANUAL

Version 1.06 MRN-141-EN

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1.01	September 2010	New version Error list		H.E. van Dijk
1.02	November 2010	Inversa Keyboard	• Menu options added	H.E. van Dijk
1.03	January 2011	All	• Replaced Key card for Chip card • Attention markers for User, Supervisor and Technician Included in menu descriptions	H.E. van Dijk
1.04	February 2011	Work instruction 401 Appendix	• Removed check waste pump tube condition from WI 401 • Appendices added: Tube connections, factory settings, maintenance schedule	H.E. van Dijk
1.05	May 2011	Introduction, Glossary	• Line "The used sedimentation pipettes are automatically washed and dried" removed • Explanation IVD added	K. Artz
1.06	August 2011	All	• Minor changes throughout manual, explanations added for user interface.	K. Artz

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1. INTRODUCTION

The **StaRRsed Blood Sedimentation Rate Instrument** (hereafter called StaRRsed Inversa) is an in vitro diagnostic medical device that automatically carries out the erythrocyte sedimentation rate analysis according to the **Westergren** method, using closed sample tubes filled with citrate or EDTA blood.

The StaRRsed Inversa is an advanced ESR system that offers many unique features and benefits over the traditional ESR procedures. Automating this method has the following advantages:

- The Westergren pipettes are always filled to the correct level.
- Using closed sample tubes reduces the possibility of contamination for the user and environment.
- Standard glass Westergren pipettes are used, in which the measurement can be corrected to a constant temperature (18 C° Celsius). Even small abnormalities can be detected over a longer period of time, irrespective of where and when the blood sample was taken.
- Every sedimentation measurement is directly linked to an identified sample, so that a manual work sheet is unnecessary. Patient ID errors are reduced to a minimum by using the bar-code reader.
- In the EDTA mode, the accuracy of dilution of EDTA blood with citrate is considerably better than manual dilution achieved either by "tipping off" or using evacuated blood collection tubes pre-filled with citrate solution.
- The data can be send to your Lab Information System.
- Minimum sample volume is 1.2 ml for the StaRRsed Inversa.
- The StaRRsed Inversa can use a variety of closed tubes from different manufacturers.

1.1. About this manual

This manual describes all necessary procedures and information required for the correct and successful use of the StaRRsed Inversa, covering installation, normal operation, user maintenance and troubleshooting.

This manual does not describe specific service related issues, such as detailed technical information and repair procedures.

In this manual, the following graphical symbols are used to draw attention to important information:

ATTENTION:
This symbol indicates warnings and other danger related information. Ignoring this information could result in personal injury, damage to the instrument or property or malfunction of the instrument.

NOTE:
This symbol indicates useful tips and other important information, that are not related to any specific danger.

NOTE:
This symbol indicates a reference to this or other product documentation.

1.2. Dilution principle

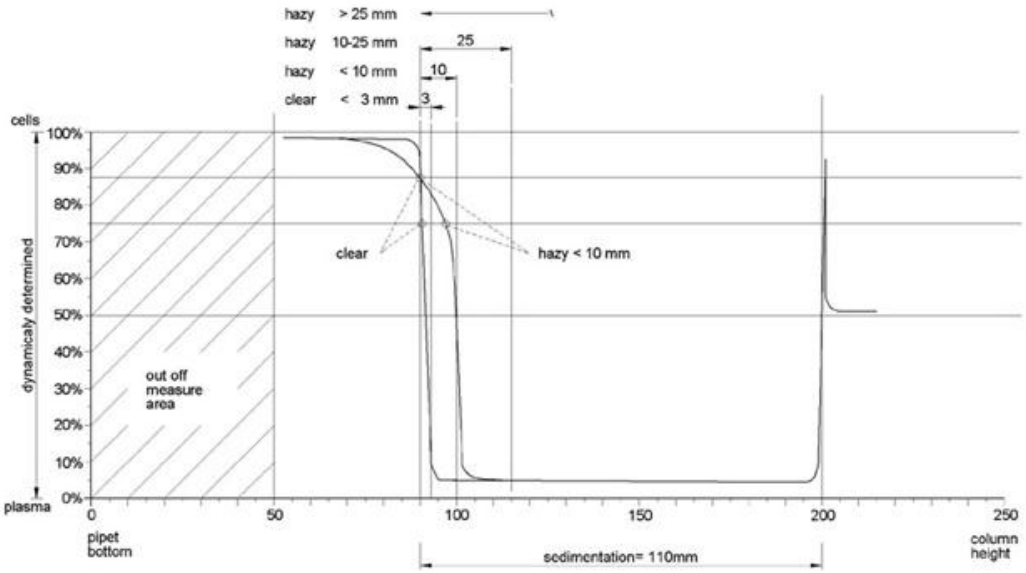
When the StaRRsed Inversa is operating in the EDTA mode, the blood sample must be diluted with sodium citrate during the aspiration process. On the StaRRsed Inversa, the dilution is achieved through a mechanical link between the syringe on the diluter and the pipette piston. The dilution ratio is 4 volumes blood + 1 volume sodium citrate diluent; accuracy ±2%.

1.3. Sedimentation measurement principle

The automatic reading of the Westergren sedimentation pipettes is carried out by moving an optical sensor along the pipettes. While the sensor is moving, a reading is made every 0.25 mm. The sensor is reading the absorption of infra red light through the Westergren pipette filled with blood. From these readings, values at a number of absorption levels are determined. All absorption figures are relative to the darkest and lightest reading (darkest = 100 % and the lightest = 0 % absorption respectively).

By definition the levels are:

87.5%	Cells/ plasma separation
75.0%	Hazy detection
50.0%	Meniscus detection



Graphic showing typical absorption values of a sample

2. INSTRUMENT DESCRIPTION

The **StaRRsed Inversa** is a semi-automatic ESR instrument. The blood sample tubes must be mixed externally before they are loaded into the sample holder one at a time. The instrument can be configured to work with pre-citrated samples (Citrate mode)or with EDTA anticoagulated samples (EDTA mode).

The sodium citrate dilution takes place in a 4+1 ratio and is achieved with ± 3% accuracy.

Twenty-four Westergren pipettes are housed in the carousel. Each is of precision bore glass.

The fill line is back-flushed with sodium citrate diluent.
Positive sample identification is achieved with a barcode-reader and takes place before aspiration of the sample.

The temperature is corrected to the standard value of 18°C and ESR's may be read after one hour or 30 minutes. A predicted one-hour result is presented in the 30-minute mode.

Results of the test are expressed in millimeters and printed on the build-in printer.

The main features of the StaRRsed Inversa are:

- Single unit with small footprint, housing all units and containers.
- Closed compartment with a carrousel holding 24 precision bore glass Westergren pipettes, measuring unit and pipette filling station.
- Build-in printer.
- Chip card system.
- Barcode reader for sample identification.
- Serial / parallel interface.
- Easy accessible keypad with light key pressure due to piezo technology.
- LCD screen.
- Battery backup memory.
- Accessories kit.

2.1. Chip card system

The StaRRsed Inversa uses a chip card system which makes it possible to employ the instrument either in a pay-per-test scheme or on customer-owner basis. Specific types of chip cards also grant access to specific instruments settings.
A chip card must always be present in the card reader to operate the instrument.

The card reader is located on the left side of the StaRRsed Inversa. Insert the chip card into the card reader with the printed side facing forward. The chip card is correctly inserted when it appears as shown in the picture:

2.1.1. Chip card type A to E

Chip cards of the types **A** to **E** are used to operate the instrument in a pay-per-test scheme. The chip cards contain a certain amount of credits units. How many tests can be performed with this amount of credits depends on the configuration which is made by the local StaRRsed Inversa dealer. The following amounts of credit units are available:

Card type	Credit units
A	100.000
B	500.000
C	1.000.000
D	5.000.000
E	10.000.000

NOTE:
Available card types and amount of credit units per card may be subject to changes.

The total amount of credit units on the chip card is transferred to the StaRRsed Inversa at once and the chip card is then rendered void. It is not possible to use the same chip card to transfer credits to more than one instrument.

This type of card is dealer dependent. The instrument only accepts chip cards of the dealer to which the instrument is configured.

2.1.2. Chip card type Q

Chip cards of type **Q** are used to operate the instrument in ownership without credit limitations and can only be used on instruments which are configured to accept the **Q** chip card.

2.1.3. Chip card type S

Chip cards of type **S** ("Supervisor card") are used by lab supervisors to grant them access to important instrument settings. When this type of chip card is inserted in the card reader, a PIN code must be entered to unlock the protected menus.

2.1.4. Chip card type T

Chip cards of type **T** ("Technician card") are used by service technicians to install and prepare the instrument for routine operation and to perform service functions. When this type of chip card is inserted in the card reader, a PIN code must be entered to unlock the protected menus.

2.2. Technical specification

Technical specifications for the StaRRsed Inversa:

StaRRsed Inversa instrument models:

Model	Model name	Catalogue number
	StaRRsed Inversa 24M	**BANG109000**

ESR method:

ESR method	Westergren method
Temperature compensation method	R.W. Manley: J. clin Path (1957), 10, 354
30 minute method	R. Rogers: Medical Laboratory World 1994
Allowed blood specimen types	• For EDTA mode: Whole blood with < 1% EDTA anticoagulant. • For Citrate mode: Whole blood (4 vols.) with sodium citrate anticoagulant-diluent (1 vol.)
Automatic dilution	4 vols. blood + 1 vol. sodium citrate diluent (3.2% NaCl); accuracy ±2%
Reported result	mm/hr

Reagents:

Reagents used	QRR 010931 Diluent QRR 010946 X-Clean

Blood volume:

Aspirated blood volume per sample	1.2 ml in EDTA mode 1.4 ml in Citrate mode

Sample tube types:

Sample tube types	Most commonly used brands/types. Closed tubes with concentrical cap only.
	• Total length: 73 ... 93 mm • Body diameter: 11.5 ... 15.5 mm • Cap diameter: 13 ... 18 mm

Barcode reader:

Barcode reader type	CCD.
Reading capabilities	Most common barcode labels
	Code39, ITF, Industrial 2 or 5, CodaBar,
	EAN/UPC and CODE128.

StaRRsed Inversa power requirements:

Mains voltage	115 - 230V AC	50-60Hz
Fuse (20 x 5 mm)	Slow blow 230V	1.6 Amp
	Slow blow 115V	2.5 Amp
Power consumption	Standby	30 VA
	Maximum	100 VA
Heat output	Standby	16 Watt
	Full operation	30 Watt

StaRRsed Inversa environment:

Sound level	Less than 58 dBA
Environment temperature	18 - 28 °C
Relative humidity	10-90%

StaRRsed Inversa overall dimensions:

Dimensions	Width	324 mm
	Height	771 mm
	Depth	529 mm
	Weight (without fluids)	23 kg

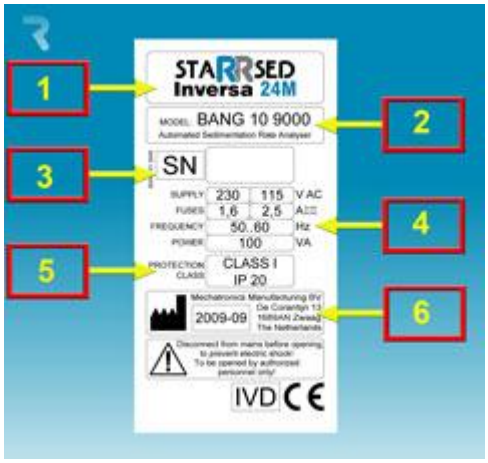
StaRRsed Inversa table size:

Min. table size	Width	600 mm
	Depth	750 mm

2.2.1. CE Mark StaRRsed Inversa

The CE Mark is found on the Mechatronics instrument identification plate, an illustration of which is shown below with explanations.

The instrument identification plate is fitted at the left side of the rear panel of the StaRRsed Inversa.



Explanation:

1. Instrument name StaRRsed Inversa
2. Instrument type and model
3. Instrument serial number
4. Electrical information
5. Protection class
6. Manufacturer information and Date of manufacture

2.3. Accessories kit

The StaRRsed Inversa comes with an accessories kit. For a complete list of the the contents of accessories kit, see ***Appendix - Article reference list Inversa*** (on page 140)

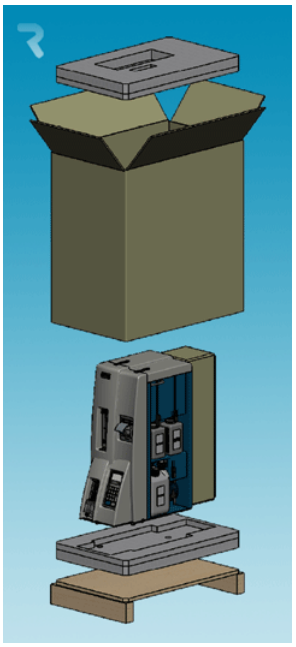
3. INSTALLATION

Before unpacking the StaRRsed Inversa, we recommend that the packaging should be checked for damage. Any damage must be reported to the distributor.

Follow the next installation instruction steps.

3.1. Unpacking Compact system

1. Cut the binding of box and take out the top protection cover.
2. Remove the out box.
3. Remove the accessories box.
4. Remove the plastic bag from the StaRRsed Inversa.
5. Lift the StaRRsed Inversa from the bottom protection cover onto a table.



3.2. Install at chosen location

Install the StaRRsed Inversa in a location with the following specifications,

1. Avoid direct sunlight shining on the StaRRsed Inversa.
2. Avoid droughts which may cause temperature changes.
3. Place the StaRRsed Inversa on a stable table, with no nearby vibration.
4. Do not place in direct airflow of an air conditioning unit.
5. Place the instrument on a **stable table**, with no nearby vibration.
6. Leave a space of approximately 15 centimeters between the back side of the instrument and the wall to allow warm air to escape and to connect or run interface cables.
7. Level the instrument by using the three adjustable feet and the leveling-gauge, which is situated at the carousel.

3.2.1. Table size

StaRRsed Inversa table size:

Min. table size	Width	600 mm
	Depth	750 mm

3.3. Start-up the first time

Before using the StaRRsed Inversa for the first time, the following items must be attended.

1. Install the stainless steel drip plates under the carousel and needle unit (slide into position).
2. Make sure the tube is installed in the pinch valves at the needle assembly.
3. Connect mains, switch ON the StaRRsed Inversa.
4. Reagents preparation.
5. Set-up and checking the General settings.
6. Check the temperature sensor is Set room temperature.
7. Check barcode reader readability of the barcode reader.
8. Check the Pipette position.
9. Priming the fluid system.
10. Run first END_OF_DAY WASH.
11. Check for possible leaking pipettes during the Fill and Clean.
12. Start filling the carousel with blood samples and check for leaking pipettes.

4. STANDARD OPERATING PROCEDURES (S.O.P.)

In this section the following issues can be found:

- Basics of Bio safety
- S.O.P. for working with bio hazardous materials
- Safety warning
- StaRRsed Incident Report
- E.C. Declaration
- Labels and stickers on containers

4.1. Basics of Bio safety

Basic rules on bio safety in a laboratory;

- Wash hands after handling biological materials, removing gloves, or before leaving work area.
- Don't eat, drink, etc. in the work area.
- Never mouth pipette.
- Take extreme precautions when sharps must be used. Dispose sharps carefully and properly.
- Conduct procedures likely to create splashes, sprays, or aerosols within a biological safety cabinet that is certified annually.
- Decontaminate work surfaces at least daily.
- Decontaminate waste materials before disposal.
- Wear a BUTTONED lab coat to protect street clothes.
- Wear gloves when hands may contact potentially infectious materials, contaminated surfaces, or equipment.
- Wear eye/face protection if splashes or sprays are anticipated during work outside a biological safety cabinet.
- Transport materials outside of the laboratory using secondary containment and a cart. Avoid public areas during transport.
- Transfer materials to and from the MCG according to federal and international regulations.
- Be familiar with written instructions for laboratory procedures and proper responses to emergencies.
- Report spills, exposures, illnesses, and injuries immediately.

4.2. S.O.P. for working with bio hazardous materials

Purpose:

To inform and educate all engineers that work with biohazards
Effective Date: July 27, 2004

4.2.1. Facts and definitions:

Biological hazards are present in all human and animal tissues and body fluids.

The "normal" research activities carried out in a blood laboratory expose workers to human blood, urine, sweat, semen, saliva and muscle tissue.

For the purpose of assessing risk, we assume that all volunteers to our clinical studies are not normal healthy individuals, and take appropriate precautions.

We remain aware at all times that increased knowledge of disease transmission and occupational hazards may result in situations currently considered safe to be reclassified as having risk.

"Universal Precautions" describes a set of procedures for dealing with subjects based on the assumption that they are positive for blood borne pathogens. Other precautions are necessary to prevent exposure to potential respiratory diseases.

4.2.2. Medical requirements:

Routine personal medical assessments are advised at regular intervals (yearly) for all personal exposed to potential biohazard.
Immunisation for Hepatitis B is recommended for everyone who is taking blood samples or dealing with human blood or bodily fluids.

4.2.3. General laboratory practices:

The laboratory is a shared facility; it must be booked in advance with the Technician in Charge. All users must follow all Departmental Safety Guidelines and Bio safety Policy.
Each user is responsible to leave a clean, disinfected and tidy work place.
All biohazard waste must be properly disposed.

4.2.4. Specific laboratory practices and requirements:

Biohazard waste:

Dispose blood tubes into a biohazard sharps container.
Dispose sharps into a biohazard sharps container.
All other bio hazardous waste is to be deposited into a biohazard bag.
All bio hazardous waste is deposited into the Medical Waste Management (MWM) bin for pick up.

Decontamination procedures:

Routine: At the end of each experiment, or each day, disinfect lab benches and any equipment
Spills: Small spills of biohazard material should be treated by first covering them with an absorbent paper to avoid the formation of aerosols. Disinfect the spill by slowly pouring on a disinfecting solution working from the outside to the centre of the spill in a circular motion. Leave the spill long enough for disinfection to take place (check decontaminating instructions on the disinfectant container for time) and then carefully wipe up wearing gloves.
Pick up any glass using forceps.
Once all the material has been removed disinfect the area thoroughly.
Inform the Technician in Charge of the spill.

Food:

No food or beverages will be brought into or consumed inside a blood laboratory at any time.

Accident reporting:

All accidents and injuries must be reported within 24 hours to the technician in Charge, to the Departmental Joint Health and Safety Committee and to the Department of Environmental Health and Safety using an Incident Report from the main office or the Technician in Charge.

Laboratory access:

Access to the haematology laboratory is limited to persons who are directly involved with the testing equipment. Children are not permitted in the laboratory.

Personal protective equipment:

Laboratory and maintenance personnel are expected to use a laboratory coat while working in the blood laboratory.
We advice the use of non-canvas closed-toe shoes wherever there is a potential for foot injury from hazardous materials or from small physical objects.
Personal outer clothing should not be stored in the blood laboratory.
Lab coats worn in the blood laboratory should not be worn outside of the blood laboratory and should not be stored with personal outer clothing, to avoid transfer of contaminants.
Gloves are considered contaminated after ones wearing. Avoid contamination of work surfaces with gloves. Dispose of gloves into a biohazard container.
The use of eye protection is advised while processing samples.
Remove and properly dispose of gloves and wash hands before leaving the laboratory.

4.3. StaRRsed Incident Report

StaRRsed Incident Report

Environmental Health and Safety plan

Important - Complete this form within 24 hours of the incident and FAX to Mechatronics: +31 (0) 229 - 24 15 34					
Last Name:	First name:		Initial:	Company:	
Student – Visitor - Employee	Occupation at time of injury		Years exp. in this occupation		
Date of incident	20_ _-_ _-_ _	Time of day _ _-_ _	Date Reported	20_ _-_ _-_ _	Time of day _ _-_ _

Description of incident	Type of incident	
State exactly the sequence of events leading to the incident; where it occurred; What the person was doing; the size, weight and type of equipment or materials involved; etc.	Incident involved results	☐
	Injury	☐
	First Aid Health Care [Medical Aid]	☐
	Other	☐

Names and addresses of witnesses:

Contributing Factors: What conditions contributed to the incident? Number the factors in order of importance.

Details of property damage if any:

Explanation of contributing factor[s]:

Corrective measures: Actions to prevent incident recurrence

Checkmark actions taken to prevent recurrence; More than one item may apply.

1 Reinstruct person involved	4 Improve personal protective equipment	7 Install guard or safety device	10 Inform all department supervision
2 Reassign person	5 Repair or replace equipment	8 Improve work procedure	11 Discipline persons involved
3 Order job safety analysis	6 Correct congested area	9 Check with manufacturer	1 2 Other (explain)

Describe actions taken to prevent recurrence:

Who is the attending physician?	
Occupational Health Services	
Organisation / Hospital	
Treatment of injury	
Name of person reporting incident	Signature of person reporting incident

FS300 - StaRRsed Incident Report V 0.1 - August 2004

Issued by the Service Department of Mechatronics.

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4.4. E.C. Declaration StaRRsed Compact

Mechatronics Manufacturing B.V.

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V.A.T. number : NL 8048 22 979 B01
C.o.C. number : 36048153 (Hoorn)

Banker : Rabobank
Account number : 3716.23.928
Swift-address : RABO NL 2U
IBAN : NL41 RABO 0371 6239 28

E.C. DECLARATION OF CONFORMITY

Herewith we declare that:

the Erythrocyte Sedimentation Rate Analyser:

StaRRsed Inversa 24M

- Is in conformity with the requirements of the following EC directives:

98 / 79 / EC	**IVD devices**
2006 / 42 / EC	**Machinery**

- The following harmonized standards have been applied:

EN 12100-1,	Safety of machinery - Part 1: Basic terminology, methodology
EN 12100-2,	Safety of machinery - Part 2: Technical principles
EN 61010-1,	Safety requirements for electr. equipm. for meas., control, and lab. use - General requirements
EN 61010-2-101,	Safety requirements for electr. equipm. for meas., control, and lab. use - Particular requirements for in vitro diagnostic (IVD) medical equipment
EN 591,	Instructions for use for in vitro diagnostic instruments for professional use
EN 980,	Symbols for use in the labelling of medical devices
EN ISO 14971,	Medical devices - Application of risk management to medical devices
EN ISO 13485,	Medical devices - Quality management systems - Requirements for regulatory purposes

The CE mark is first applied on this instrument model in 2009.

Zwaag, The Netherlands
February 22, 2010

R. Metselaar
Managing director,
Mechatronics Manufacturing BV

Conditions:
By the ORGALIME GENERAL CONDITIONS (S92) of August 2000.
Any other conditions are herewith explicitly rejected by us.

FME CWM

KEMA CERTIFICATE EN ISO 13485:2003

KEMA CERTIFICATE ISO 9001:2000

5. LABELS AND STICKERS

5.1. Stickers for the onboard reagents bottles

These stickers are used on the onboard reagent bottles. For more information about these bottles see sections:

- ***Waste disposal*** (on page 103)
- ***Diluent*** (on page 98)
- ***X-Clean*** (on page 98)

5.2. Stickers of the reagents containers

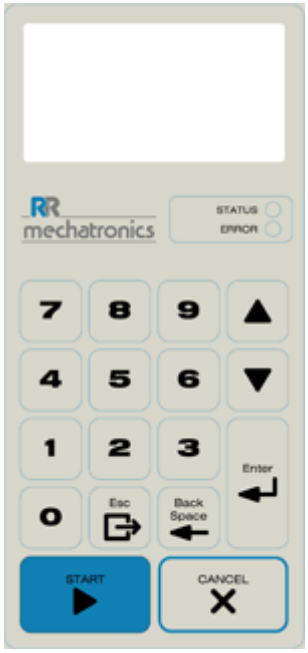
6. SAFETY WARNING

When there was an incident with the StaRRsed Inversa which caused damage to the instrument, please notify your superior and your local equipment dealer before you continue using the instrument.

Example:

- A collision with a moving object
- Something falling on the instrument
- Somebody falling into or onto the Sedimentation instrument
- Liquids spilling into the instrument

7. USER INTERFACE



[ARROW UP] key

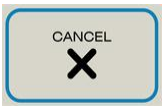
[ARROW DOWN] key

[ENTER] key

[BACKSPACE] key

[ESC] key

[START] key



[CANCEL] key

7.1. Navigating through the menus

The main menu is displayed after start-up.

The bottom line of the display shows which keys are valid in the context of the selected menu or function.

To **start** functions or access other menus, you can either:

- Press the required row number on the keyboard. The function or menu is activated automatically.
- Scroll to the required row using the arrow keys and press **[ENTER]** to activate.

The menus SETTINGS and SERVICE contain **more functions** than can be displayed on one screen.

To access the next screen you can either:

- Press number **7** on the keyboard.
- Scroll to row "7 NEXT" using the arrow keys and press **[ENTER]**.
- When the cursor is on row "7 NEXT", scroll further down with **[ARROW DOWN]**.

To **leave** these menus, you can:

- Press **[ESC]** to return to the previous screen.
- When the cursor is on the top row ("1"), scroll further up with **[ARROW UP]** to return to the previous screen.
- Keep **[ESC]** pressed for 2 seconds to return directly to the main menu.

The default settings in the different menus are printed in Bold

In the following tables, a check mark (√) indicates which menus and functions are accessible for which type of operator. The access depends on the use of the appropriate chip cards.

- **U** is accessible for the User
- **S** is accessible for the Supervisor
- **T** is accessible for the Technician

		U	S	T
		√	√	√

Menu 1 SAMPLE MODE

Menu 2 PATIENT/POS. DATA

Menu 3	END_OF_DAY WASH
Menu 4	PRIME
Menu 5	SETTINGS
Menu 6	SERVICE
Menu 7	CARD & CREDITS

7.2. Start-up screen

The start-up screen is shown for approx. 5 sec. after the StaRRsed Inversa is switched on. The software version appears at the bottom of this screen.

7.2.1. Start Printout after Switch ON

When a card type A - E or a Q card is present in the card reader of the StaRRsed Inversa the following information will be printed after Switch ON.

A Switch ON configuration example printout after switching the StaRRsed Inversa ON.

Column 1	Column 2	Column 3
	StaRRsed Inversa24M	

Line 1	S/N:		123456789ABC
Line 2		30-06-2011	09:00:45
Line 3		Dealer Code:	1234567
Line 4		D-factor:	0
Line 5		Credits:	-
Line 6		Total counts:	12345
Line 7		Serv. count:	1234
Line 8			123456A00087 123456Q00002

In line 8 the serials numbers of the used cards are display.

7.3. Warning screen Prime

PRIME	
LAST - PRIME MORE THAN 12H AGO! PRIME NOW? (RECOMMENDED)	
= ESCAPE	= YES

This warning screen appears when the StaRRsed Inversa has been idle or switched off for more than the indicated hours. Press **[ENTER]** to start the function. This will ensure that the fluid lines are correctly filled with diluent. This function can also be started manually at a later time.

7.4. Warning screen End of day wash

END_OF_DAY WASH
LAST - END_OF_DAY WASH MORE THAN 12H AGO! END_OF_DAY WASH? (RECOMMENDED)
= ESCAPE = YES

This warning screen appears when the End-of-day wash was not done after the last sample run and the StaRRsed Inversa has been idle or switched off for more than the indicated hours. Press **[ENTER]** to start the function. This will ensure that the pipettes are cleaned thoroughly. This function can also be started manually at a later time.

7.5. Menu structure StaRRsed Inversa

Note: Software version Main 1.30, Slave I.O 1.15, Display 2.14

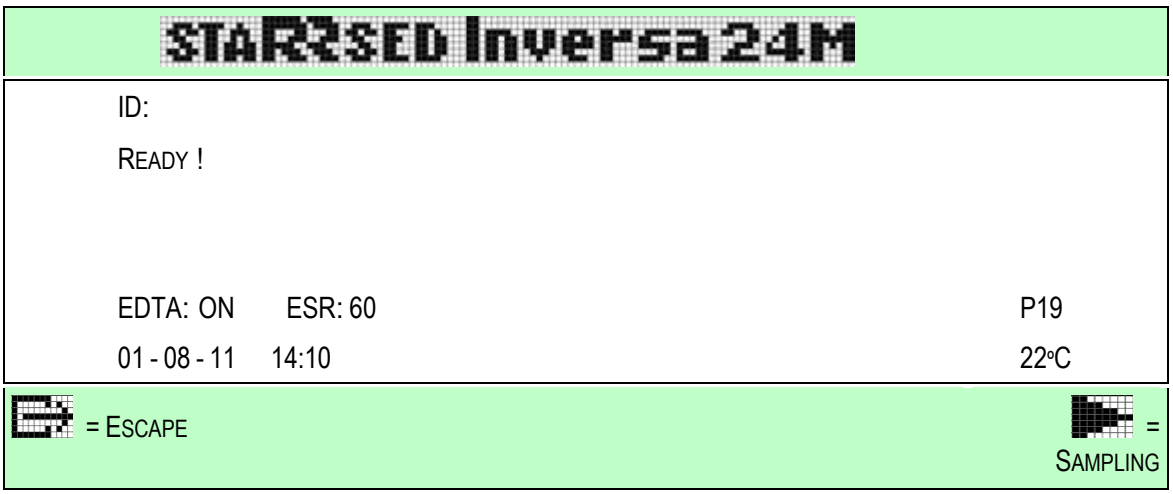
7.5.1. User menu section

User functionality can be accessed with all types of Chip cards.

7.5.1.1. Main menu

		U	S	T
1	SAMPLE MODE	√	√	√
2	PATIENT/POS. DATA	√	√	√
3	END_OF_DAY WASH	√	√	√
4	PRIME	√	√	√
5	SETTINGS	√	√	√
6	SERVICE	√	√	√
7	CARD & CREDITS	√	√	√
=SELECT				

7.5.1.2. Sample screen



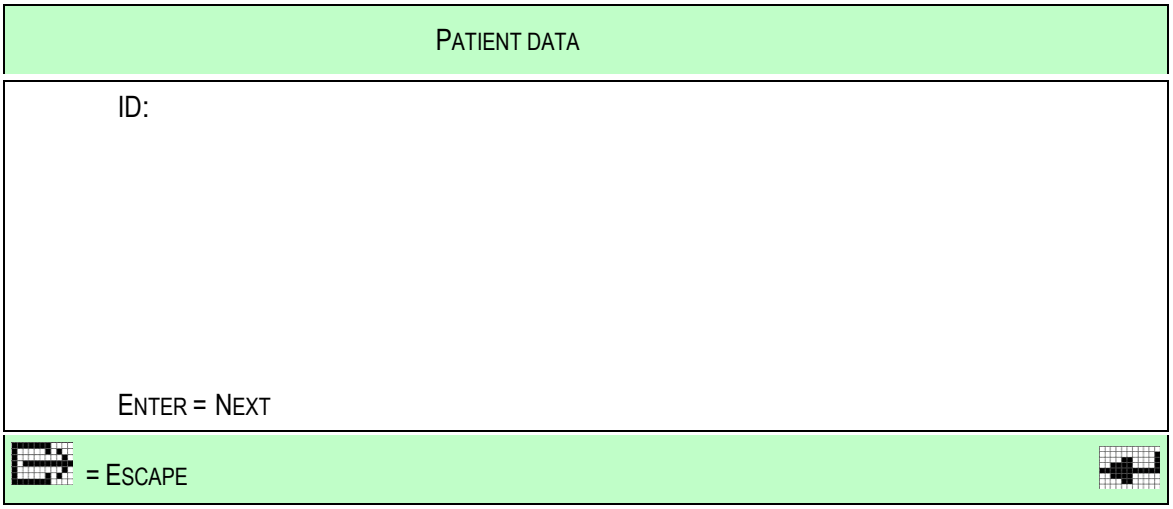
The sample screen shows the current sample ID and status.

7.5.1.3. Menu 2 Patient / pos. data (User)

		U	S	T
1	PATIENT DATA	√	√	√
2	POSITION DATA	√	√	√
3	PRINT DATA	√	√	√
4	PRINT RAW DATA	√	√	√
5	SEND DATA	√	√	√
6				
7				

= ESCAPE =SELECT

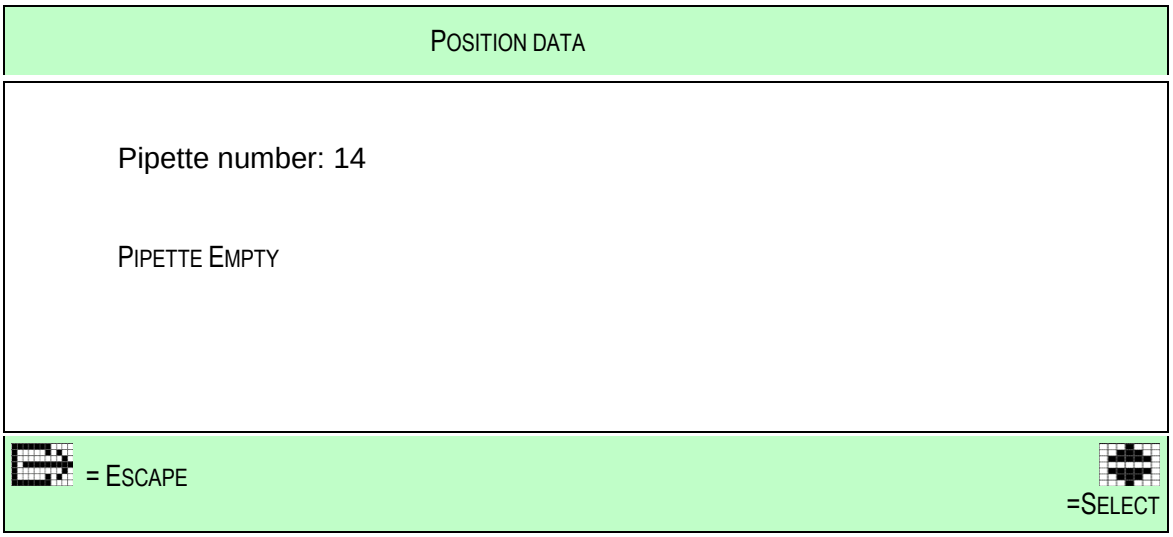
7.5.1.3.1. Menu Patient data



Use this function to check the sample status of a particular patient in the data storage of the StaRRsed Inversa.

Put the sample tube into the needle holder and press **[ENTER]** to get the patient ID from the barcode label or enter the ID manually and then press **[ENTER]**.

7.5.1.3.2. Menu Position data



Use this function to check the status of a particular pipette. Use the **[ARROW UP]** and **[ARROW DOWN]** keys to scroll through the pipettes.

7.5.1.3.3. Menu Print data

	PRINT DATA	U	S	T
1	TODAY'S RESULTS	√	√	√
2	YESTERDAY'S RESULTS	√	√	√
3		√	√	√
4	DATE	√	√	√
5				
6				
7				

= ESCAPE =SELECT

Press **[ENTER]** to start the function.

TODAY'S RESULTS
CONTINUE ?
= ESCAPE = YES

or

YESTERDAY'S RESULTS
CONTINUE ?

= ESCAPE	= YES

Use these functions to print all sample results from the selected day on the build-in printer.

7.5.1.3.3.1. Menu Date

DATE
DAY: (dd) INPUT:
= ESCAPE

Enter the day number and press **[ENTER]**. Then continue in the same way with the month, year, hour and minutes (if applicable).

Note: When there is no input during 60 seconds the input option is closed.

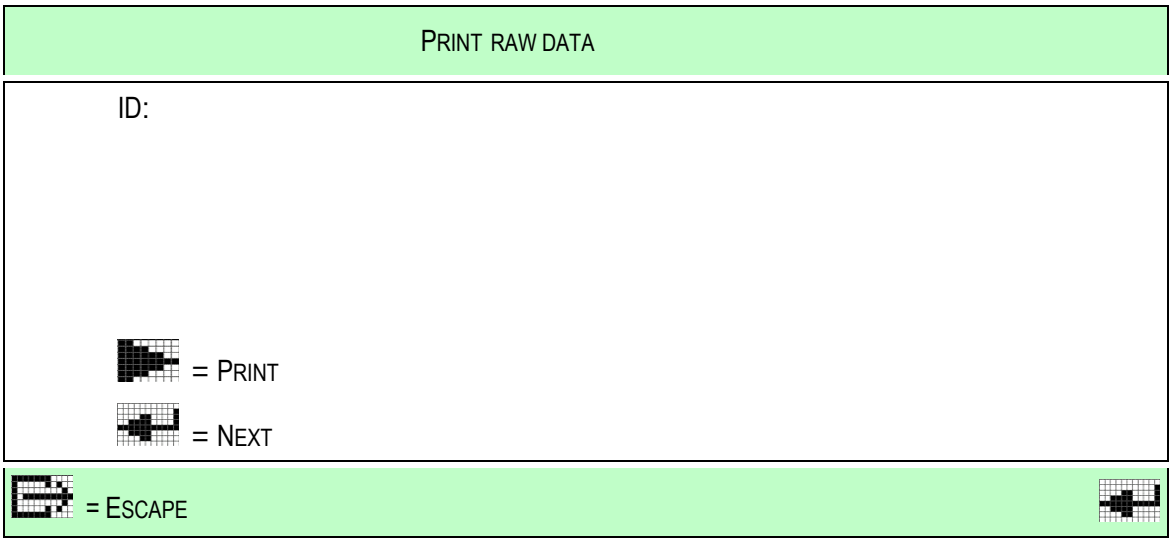
7.5.1.3.4. Menu Print raw data

	PRINT RAW DATA	U	S	T
1	PRINT DATA	√	√	√
2	PRINT GRAPH	√	√	√
3				
4				
5				
6				
7				

= ESCAPE	=SELECT	

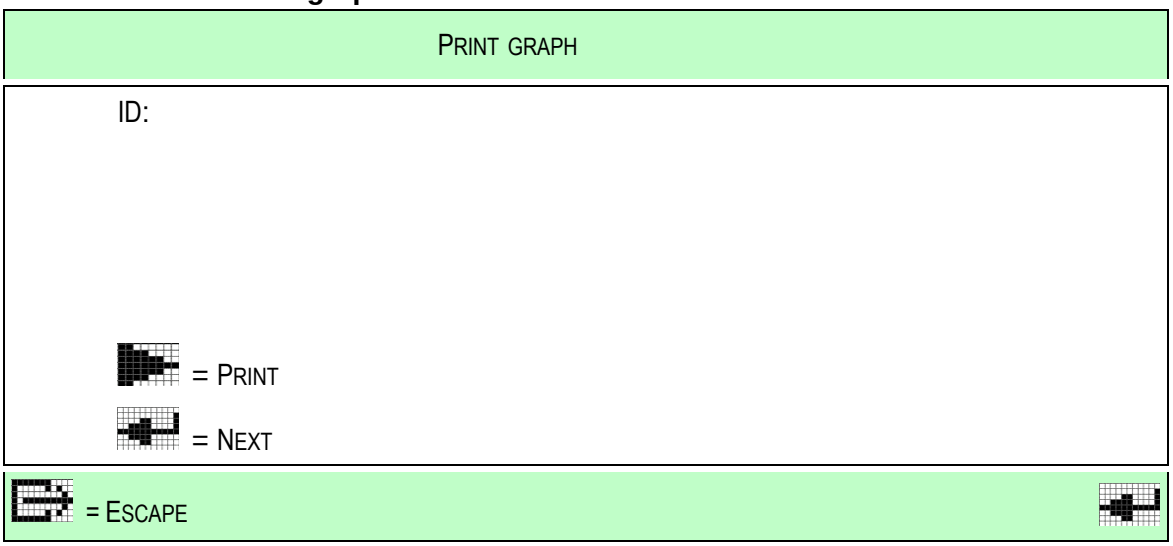
Use these functions to print the raw measurement data of a particular sample. The raw data can be used to analyse a sample in detail in case of unexpected results.

7.5.1.3.4.1. Menu Print raw data



Put the sample tube into the needle holder and press **[ENTER]** to get the patient ID from the barcode label or enter the ID manually and then press **[ENTER]**.

7.5.1.3.4.2. Menu Print graph



Put the sample tube into the needle holder and press **[ENTER]** to get the patient ID from the barcode label or enter the ID manually and then press **[ENTER]**.

7.5.1.3.5. Menu Send data

SEND DATA	
1	TODAY'S RESULTS
2	YESTERDAY'S RESULTS
3	
4	DATE
5	
6	
7	

= ESCAPE =SELECT

Press **[ENTER]** to start the function.

TODAY'S RESULTS
CONTINUE ?

= ESCAPE = YES

.

or

YESTERDAY'S RESULTS
CONTINUE ?

.

Use these functions to send all sample results from the selected day to the HOST.

7.5.1.4. Menu 3 End-of-day wash

END_OF_DAY WASH
CONTINUE ?
= ESCAPE = YES

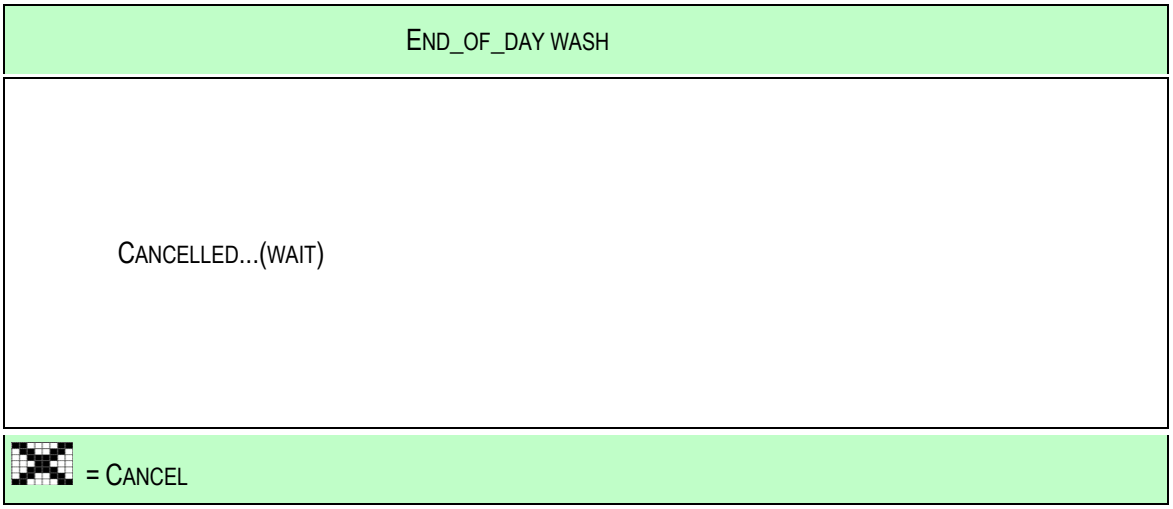
Press **[ENTER]** to start the function.

END_OF_DAY WASH
BUSY...(PLEASE WAIT)
= CANCEL

The function may be cancelled by pressing **[CANCEL]**.

END_OF_DAY WASH
ARE YOU SURE?

Yes



When the last sample is more then 12 hours ago an END_OF_DAY WASH warning is shown on the display with the recommendation to activate the END_OF_DAY WASH function.

7.5.1.5. Menu 4 Prime

Prime
CONTINUE ?
= ESCAPE = YES

.Press **[ENTER]** to start the function.

Prime
BUSY...(PLEASE WAIT)
= CANCEL

The function may be cancelled by pressing **[CANCEL]**.

Prime
CANCELLED...(WAIT)
= CANCEL

When the last prime function is more then 12 hours ago a PRIME warning is shown on the display with the recommendation to activate the PRIME function.

7.5.1.6. Menu 5 Settings (User)

		U	S	T
1	EN/DISABLE PIPET	√	√	√
2	PRINT SETTINGS	√	√	√
3				
4				
5				
6				
7				

= ESCAPE =SELECT

7.5.1.6.1. Menu En/disable pipet

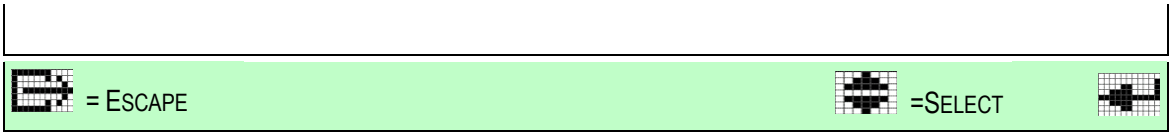
EN/DISABLE PIPET

PIPET NUMBER: 19

PIPET:EMPTY

1 O X O O O O O O O O O O 12

13 O O O O O X O O O O O O 24

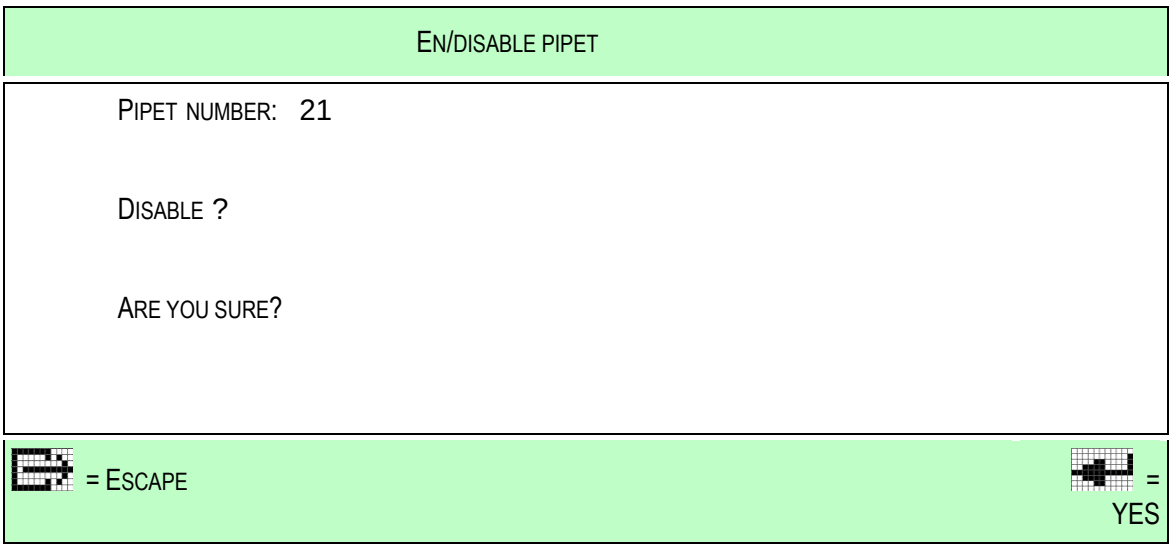


The status of the current pipette is shown at the top.
The lower part shows a representation of all pipettes in the carousel counted from left to right and from top to bottom. Enabled pipettes are marked with a dot (**O**), disabled pipettes are marked with a cross (**X**).

The StaRRsed Inversa checks automatically for leaking pipettes by observing column height warnings that may be given with the ESR results. Leaking pipettes are automatically disabled for future use and must be enabled manually.

Note: In this example, pipettes 2 and 18 are disabled.

Use the **[ARROW DOWN]** or **[ARROW UP]** keys and select the required pipette number, then press the **[ENTER]** key to toggle the setting to the opposite of the current state.



7.5.1.6.2. Menu Print settings

PRINT SETTINGS
CONTINUE ?
= ESCAPE = YES

.

Press **[ENTER]** to start the function. The instrument settings are printed on the build-in printer.

7.5.1.7. Menu 6 Service

		U	S	T
1	ERROR HISTORY	√	√	√
2	SOFTWARE VERSIONS	√	√	√
3	DISPLAY S/N	√	√	√
4				
5				
6				
7				

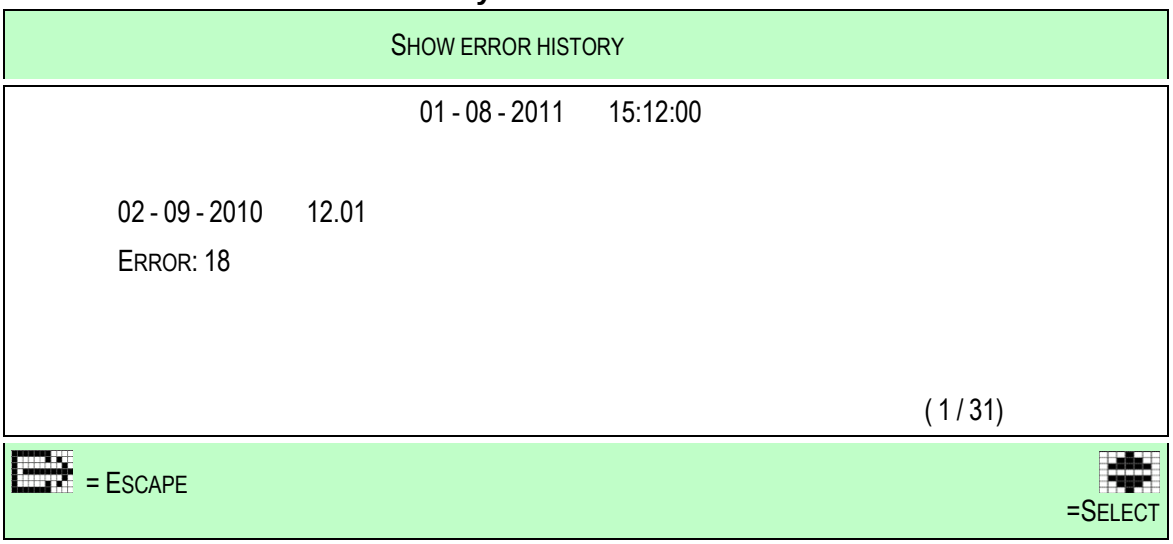
= ESCAPE =SELECT

7.5.1.7.1. Menu Error history

1	SHOW ERROR HISTORY	√	√	√
2	PRINT ERROR HISTORY	√	√	√

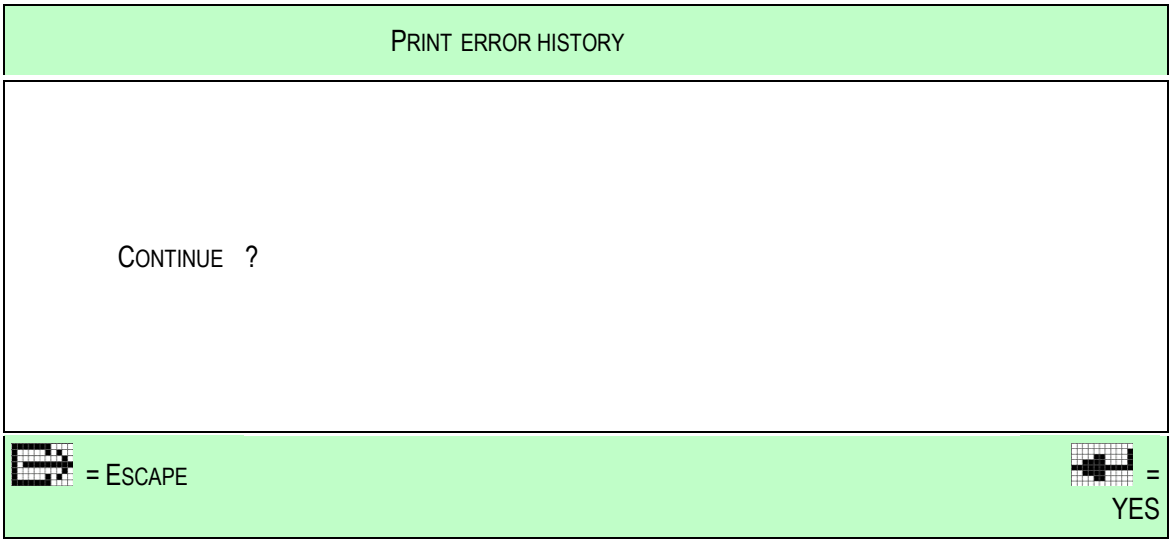
= ESCAPE =SELECT

7.5.1.7.1.1. Menu Show error history



The first row shows the current date and time. The third row shows the date and time when the displayed error occurred.
Use the **[ARROW DOWN]** or **[ARROW UP]** keys and select the next error code.

7.5.1.7.1.2. Menu Print error history



.

Press **[ENTER]** to start the function. The error history is printed on the build-in printer.

7.5.1.7.2. Menu Software versions

SOFTWARE VERSIONS
MAIN : V1.21 SLAVE (IO) : V1.11 DISPLAY : V2.11
= ESCAPE

.

7.5.1.7.3. Menu Display S/N

DISPLAY S/N
S/N: 000123456789
= ESCAPE

.

The displayed number is the instrument security number which is a security feature associated with the chip card system.

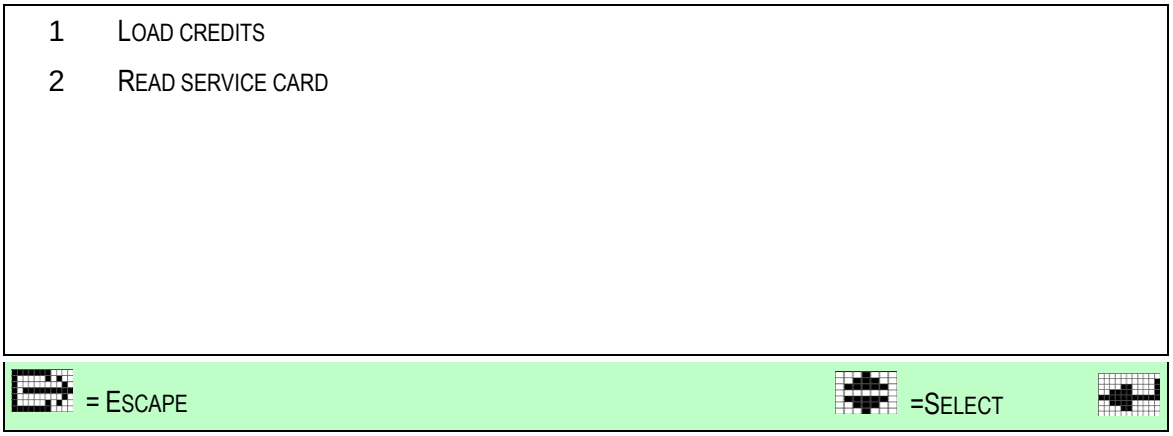
NOTE:
This **security number** is *not* the same as the **serial number** of the instrument. The serial number is printed on the instrument type label on the back of the StaRRsed Inversa.

7.5.1.8. Menu 7 Card & Credits (User)

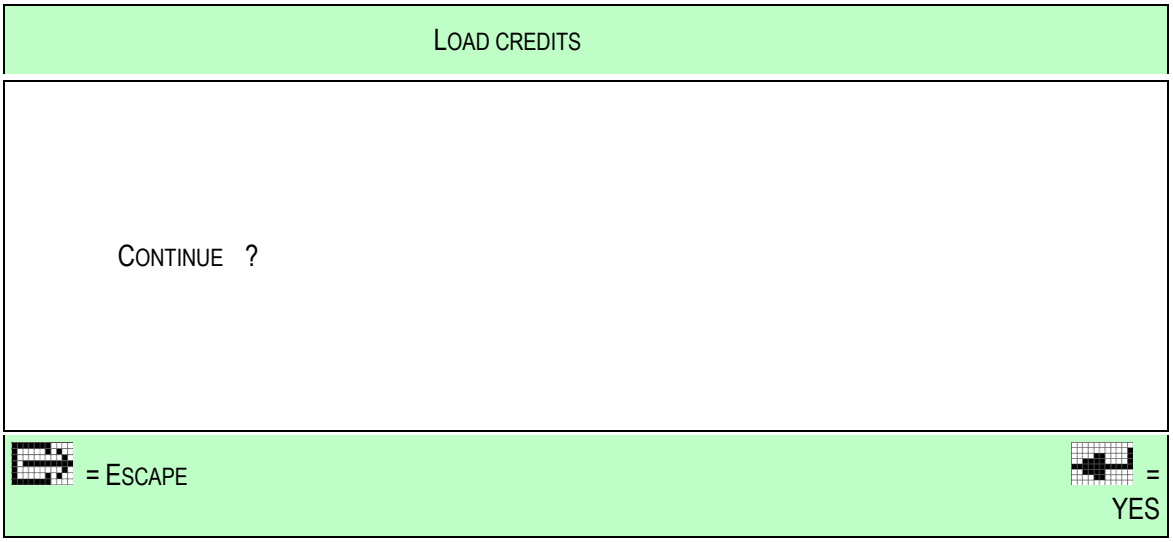
		U	S	T
1	LOAD CREDITS	√	√	√
2	READ SERVICE CARD	√	√	√

= ESCAPE =SELECT

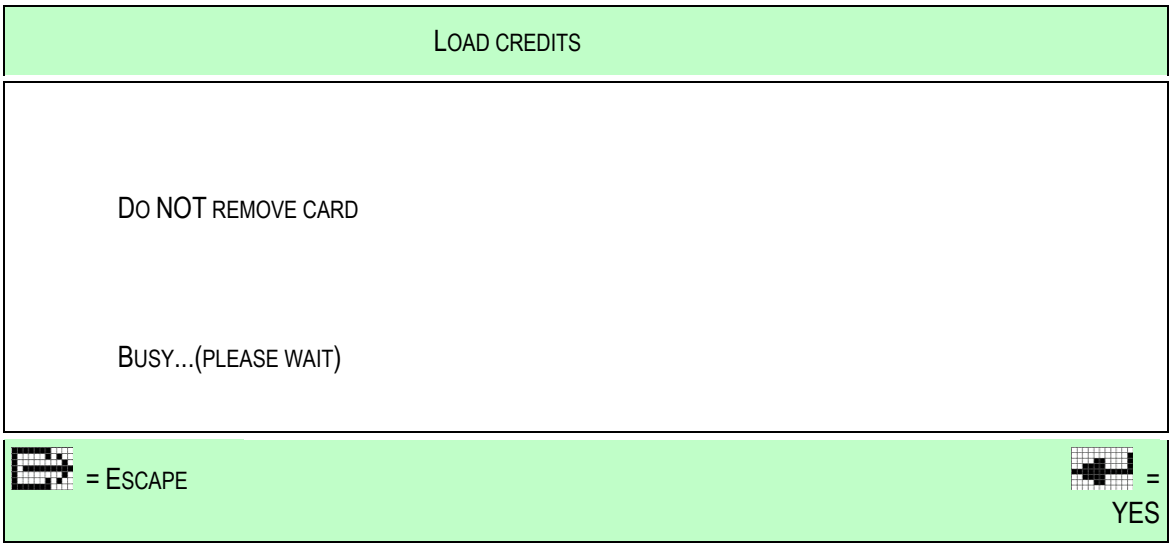
7.5.1.8.1. Menu Load credits



Select 1 LOAD CREDITS. This function is used to load credit units from a credit chip card into the internal memory of the StaRRsed Inversa.



Press **[ENTER]** to start the function.



DONE ! ! !

TYPE: Q (**Note:** This is the code letter for the type of chip card)

SN: 123456789 (**Note:** This is the serial number of the chip card)

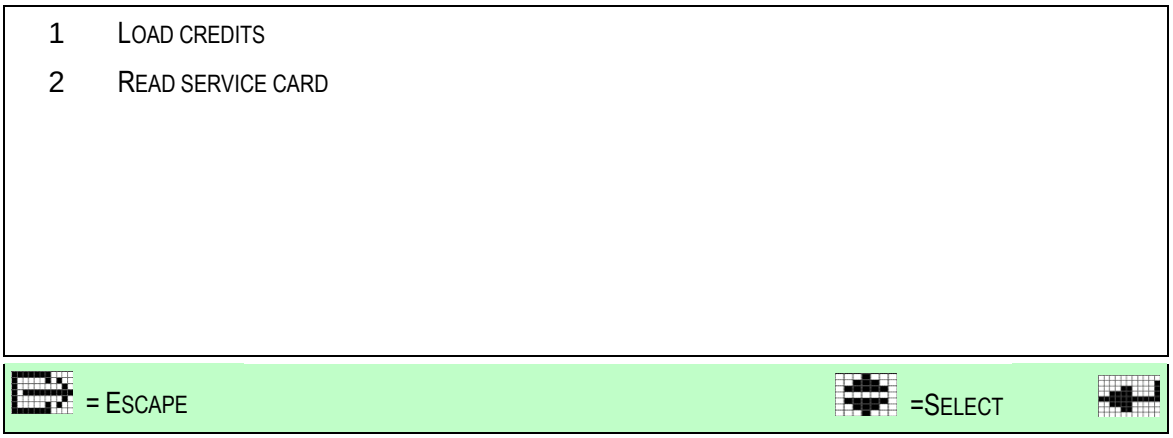
CREDITS: XXXXXXX

(**Note:** This is the total amount of available credit units in memory)

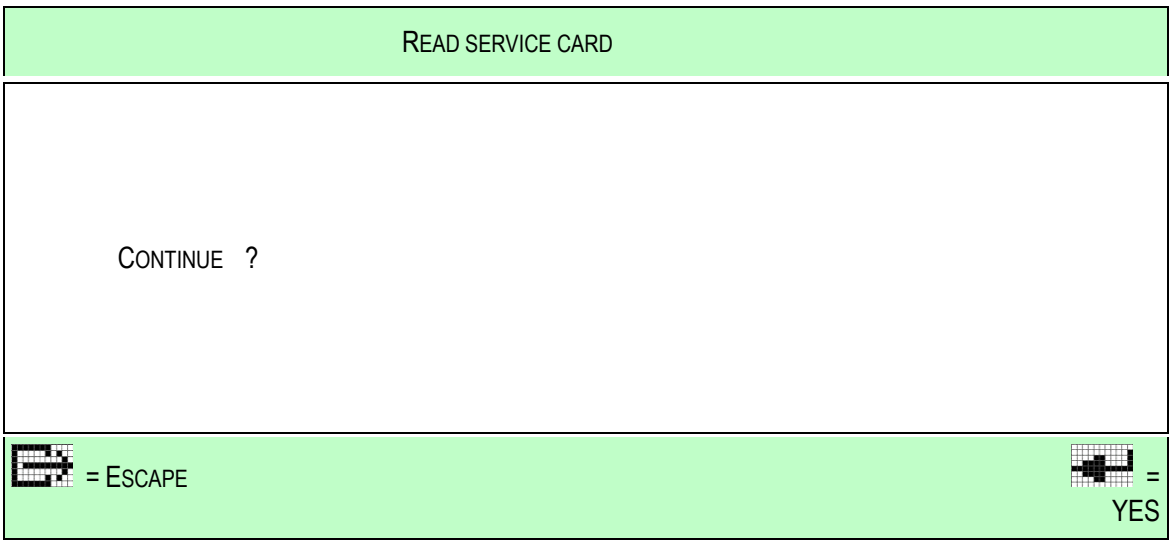
= ESCAPE

7.5.1.8.2. Menu Read service card

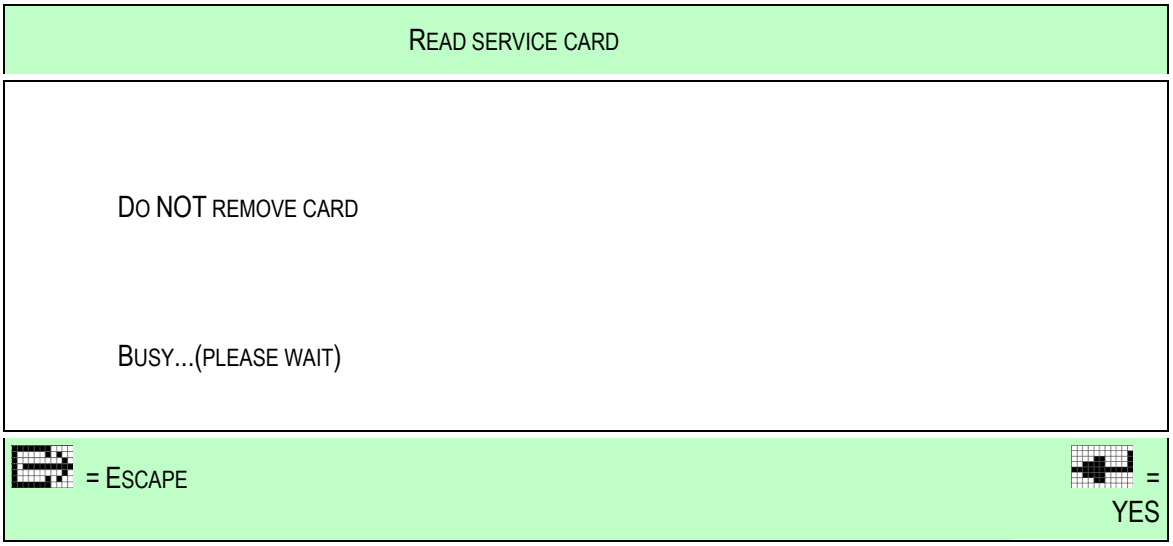
Make sure you insert a service chip card type in the chip card reader of the StaRRsed Inversa



Select 2 READ SERVICE CARD. This function is used to unlock the protected menus and functions.



Press **[ENTER]** to start the function.



READ SERVICE CARD

TYPE: S (**Note:** This is the code letter for the type of chip card)

SN:123456789 (**Note:** This is the serial number of the chip card)

PASSWORD: XXXX (**Note:** type the required password for this service chip card)

= ESCAPE

Enter the required password for the inserted type of service chip card and press **[ENTER]**. Wait until the display shows "CARD OK !".

7.5.2. Lab Supervisor menu section

Lab Supervisor functionality can be accessed with chip card type **S**.

Only the additional supervisor functions and submenus are explained in this section. For the standard user menu refer to the "***User menu section*** (on page 43)".

7.5.2.1. Menu 2 Patient / pos. data

		U	S	T
1	PATIENT DATA	√	√	√
2	POSITION DATA	√	√	√
3	PRINT DATA	√	√	√
4	PRINT RAW DATA	√	√	√
5	SEND DATA	√	√	√
6			√	√
7	DELETE DATA		√	√

= ESCAPE =SELECT

7.5.2.1.1. Menu Delete data

1	DELETE PIPET DATA		√	√
2	DELETE HIST. DATA		√	√

= ESCAPE = YES

Function 1 DELETE PIPET DATA is used to delete all data of samples currently in the pipettes. These samples have not been measured yet.
Function 2 DELETE HIST. DATA is used to delete all stored data (results) of previously measured samples.

Warning:
Using these functions will erase all of the selected data from the memory of the StaRRsed Inversa. Once erased, the data can not be recovered!

DELETE PIPET DATA

SAMPLES WILL BE LOST

ARE YOU SURE?

= ESCAPE = YES

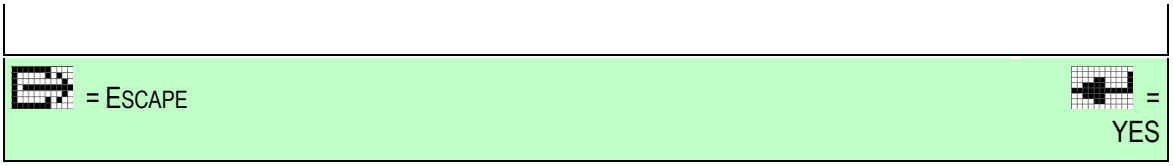
.

Press **[ENTER]** to confirm the selection and start the function.

DELETE HIST. DATA

SAMPLES WILL BE LOST

ARE YOU SURE?



Press **[ENTER]** to confirm the selection and start the function.

7.5.2.2. Menu 5 Settings (Lab Supervisor)

		U	S	T
1	EN/DISABLE PIPET	√	√	√
2	PRINT SETTINGS	√	√	√
3				
4				
5				
6				
7	NEXT		√	√

= ESCAPE =SELECT

Next submenu:

1	30 MIN. METHOD		√	√
2	EDTA MODE		√	√
3	TEMPERATURE		√	√
4	TCORR		√	√
5			√	√
6	CAROUSEL POSITION			√
7	NEXT		√	√

= ESCAPE =SELECT

Next submenu:

1	DST (**Note**:Daylight Saving Time)		√	√
2	RESULT AT LIMIT		√	√
3	PRINTER (RESULTS)		√	√
4	DATE / TIME		√	√
5	LANGUAGE		√	√
6	ESR TIME (MIN)		√	√
7	NEXT		√	√

= ESCAPE =SELECT

Next submenu:

1	PROTOCOL		√	√
2	BAUDRATE		√	√
3			√	√
4	CHECKSUM		√	√
5	ACK/NACK		√	√
6	30 MINUTE OUTPUT		√	√
7				

= ESCAPE =SELECT

To return to the previous settings screen, press **[ESC]**.
To return directly to the Main menu, keep **[ESC]** pressed until the Main menu is displayed.

7.5.2.2.1. Menu 30 min. method

30 MIN. METHOD

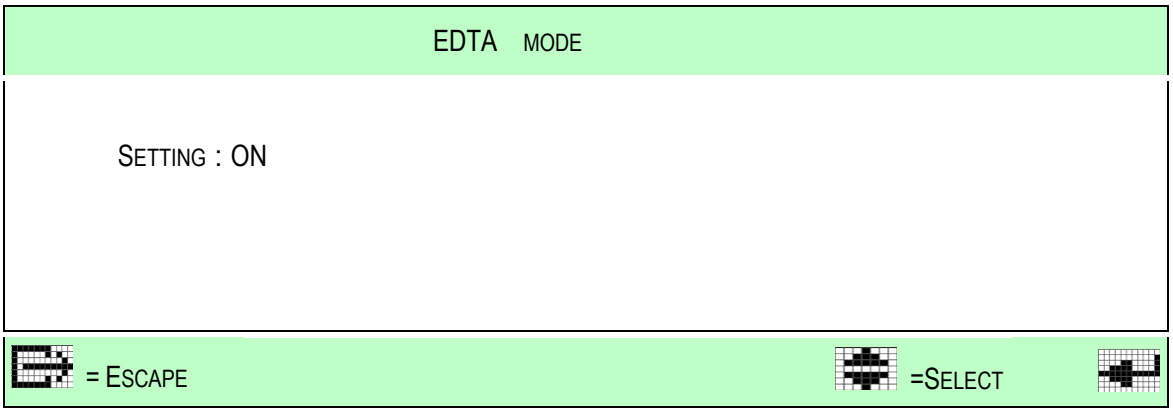
SETTING: OFF

= ESCAPE =SELECT

When this setting is ON, the pipettes are measured after 30 minutes instead of 60 minutes. The obtained reading is converted to a predicted 60 minute result.

Use the **[ARROW DOWN]** or **[ARROW UP]** keys and select the required option.
Then press **[ENTER]** to save the new setting.

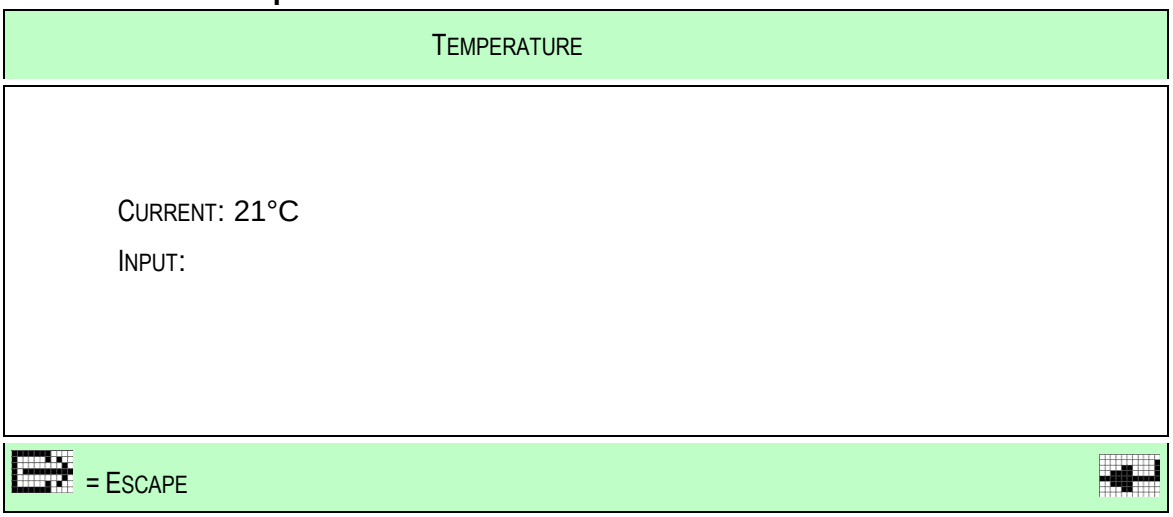
7.5.2.2.2. Menu EDTA mode



Use the **[ARROW DOWN]** or **[ARROW UP]** keys and select the required option. Then press **[ENTER]** to save the new setting.

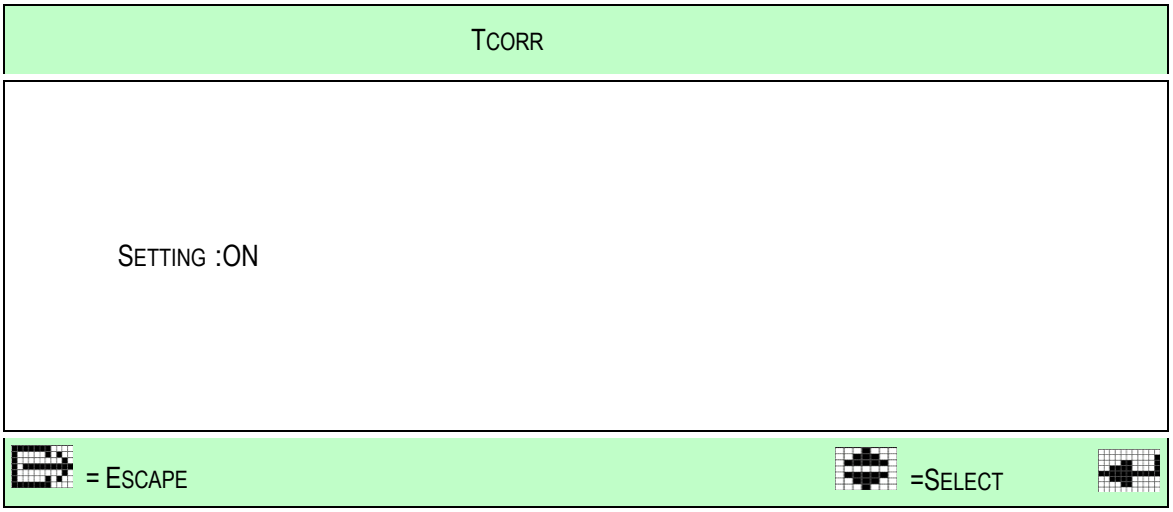
NOTE:
A small hardware modification is necessary to switch between EDTA mode and Citrate mode. See work instruction WI-405 for details.

7.5.2.2.3. Menu Temperature



The displayed value is the temperature according the build-in thermometer of the StaRRsed Inversa. Check the actual temperature near the pipettes with an external thermometer. If the values do not match, enter the correct value. Then press **[ENTER]** to save the new setting.

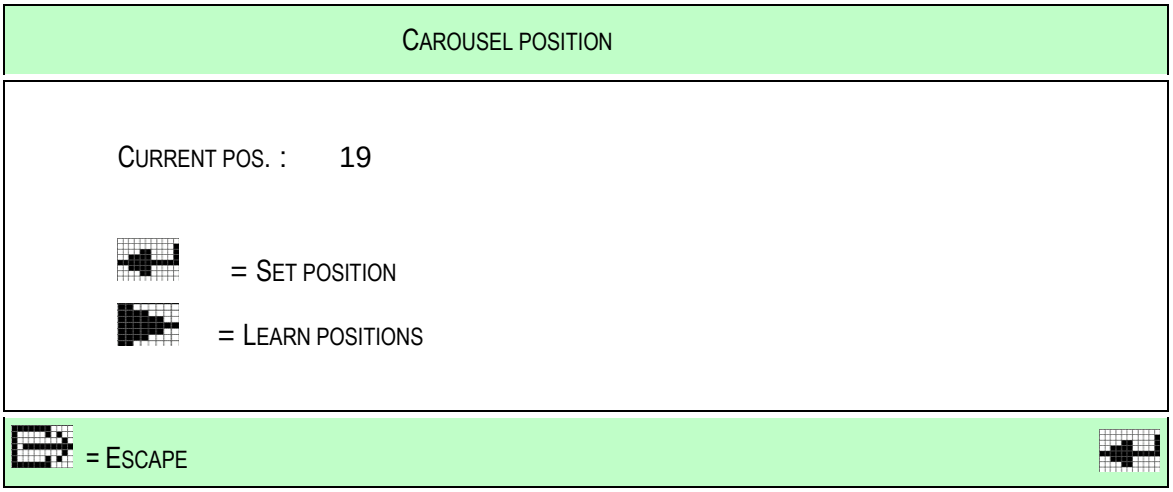
7.5.2.2.4. Menu Tcorr



This option is used to set if Temperature correction is to be applied on the measured ESR results.

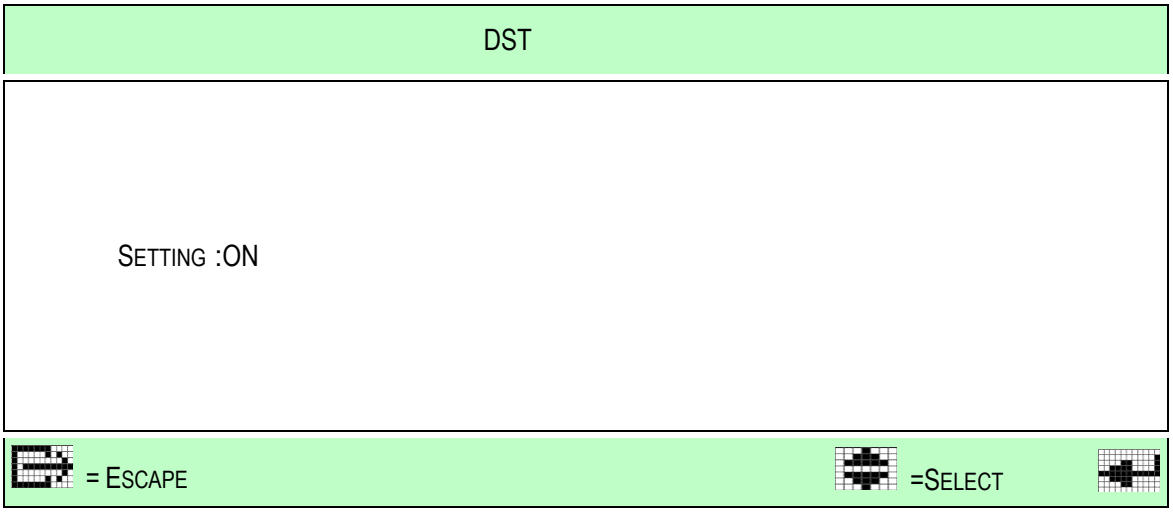
Use the **[ARROW DOWN]** or **[ARROW UP]** keys and select the required option.
Then press **[ENTER]** to save the new setting.

7.5.2.2.5. Menu Carousel position



These functions are used to reset the correct pipette positions that are stored in memory. The displayed value is the pipette number that should currently be present at the nozzle position. Press the **[ENTER]** or **[START]** key to show the Input option. Enter the pipette number which is actually present at the nozzle position and press **[ENTER]** to activate the action.

7.5.2.2.6. Menu DST

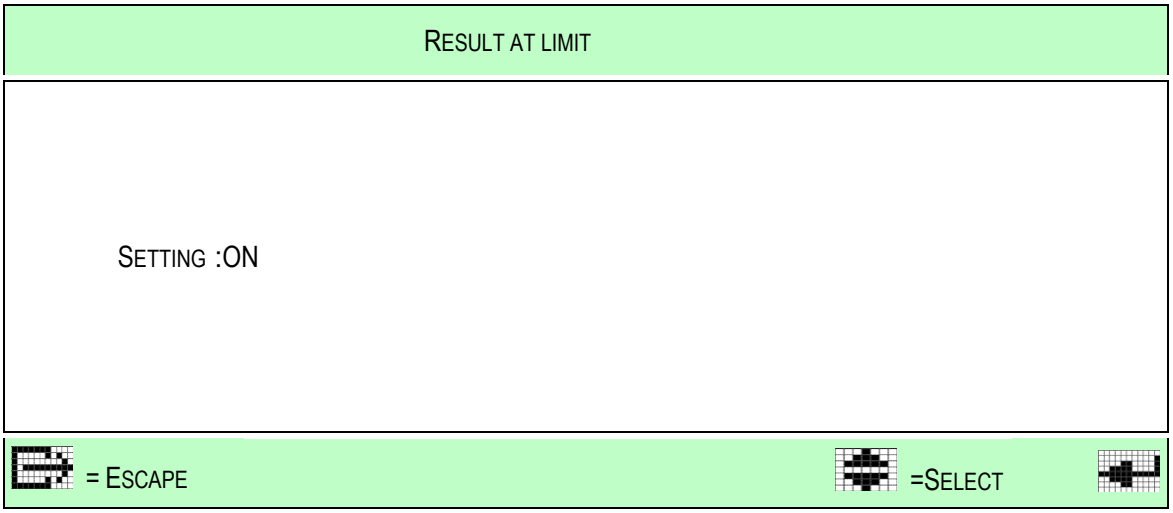


This function is used to switch the internal clock to **Daylight Saving Time** (also called *Summertime*).

Use the **[ARROW DOWN]** or **[ARROW UP]** keys and select the required option.
Then press **[ENTER]** to save the new setting.

Note: Can only be set between 03:00 and 21:00 and when the carousel is empty.

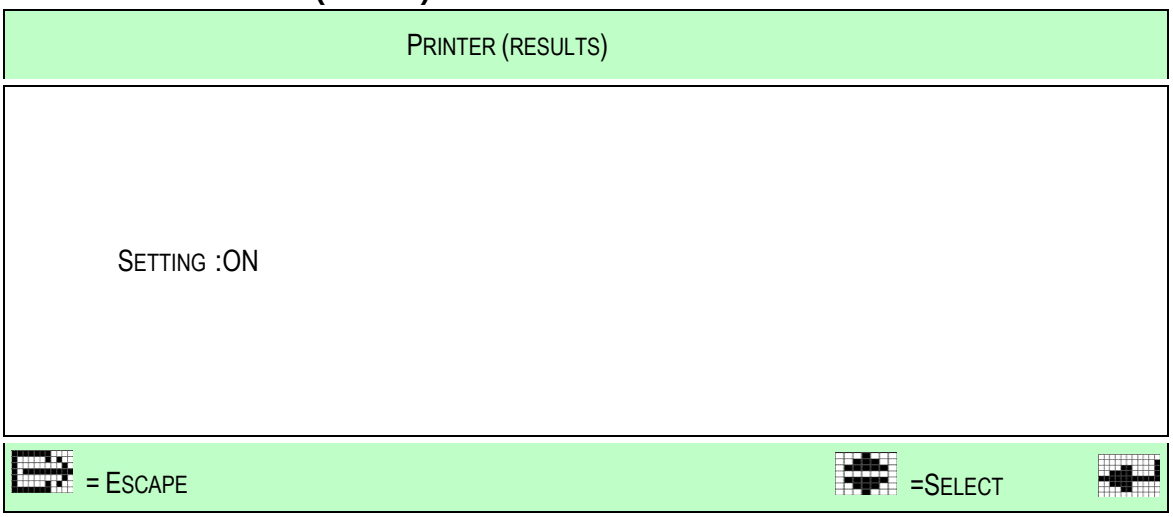
7.5.2.2.7. Menu Result at limit



See section "Results at limit errors" for details of this option.

Use the **[ARROW DOWN]** or **[ARROW UP]** keys and select the required option.
Then press **[ENTER]** to save the new setting.

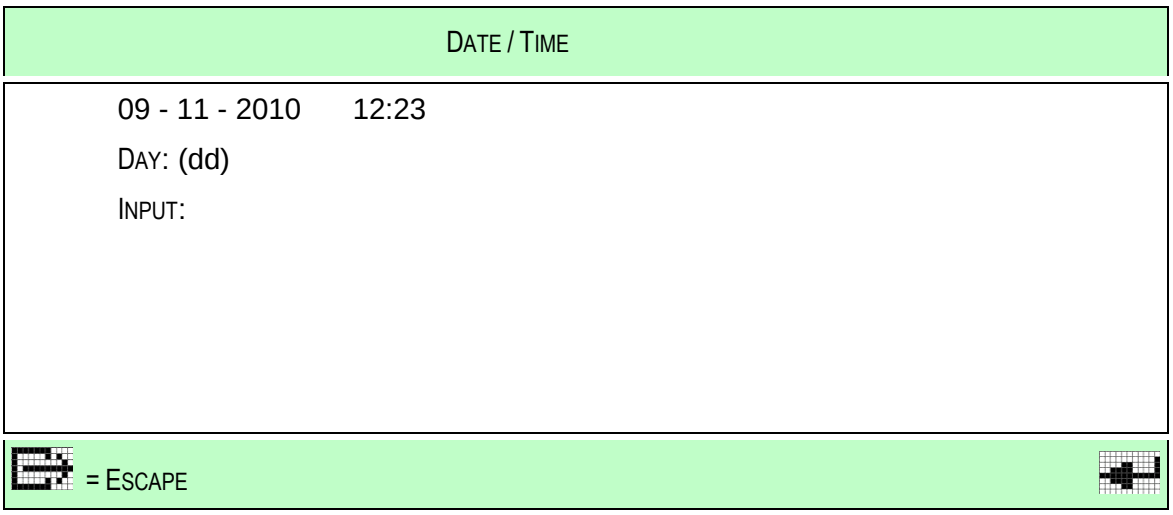
7.5.2.2.8. Menu Printer (results)



This function is used to switch if ESR results must be printed on the build-in printer. Printing may not be necessary if all results are send to a HOST.

Use the **[ARROW DOWN]** or **[ARROW UP]** keys and select the required option.
Then press **[ENTER]** to save the new setting.

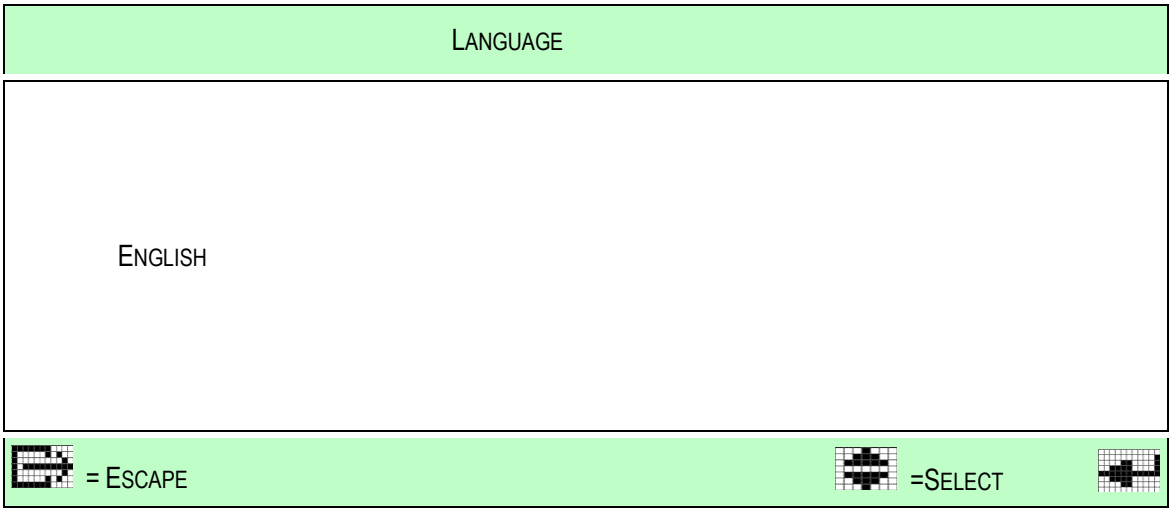
7.5.2.2.9. Menu Date / Time



To set the system date and time, enter the day number and press **[ENTER]**. Then continue in the same way with the month, year, hour and minutes.

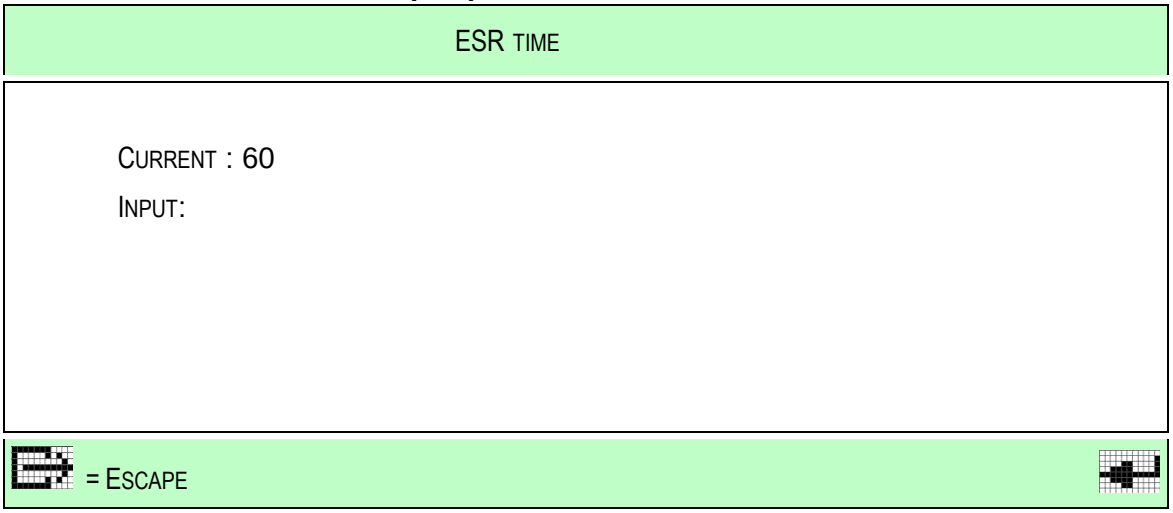
Note: When there is no input during 60 seconds the input option is closed.

7.5.2.2.10. Menu Language



Select the required language for the user interface.

7.5.2.2.11. Menu ESR time (min)

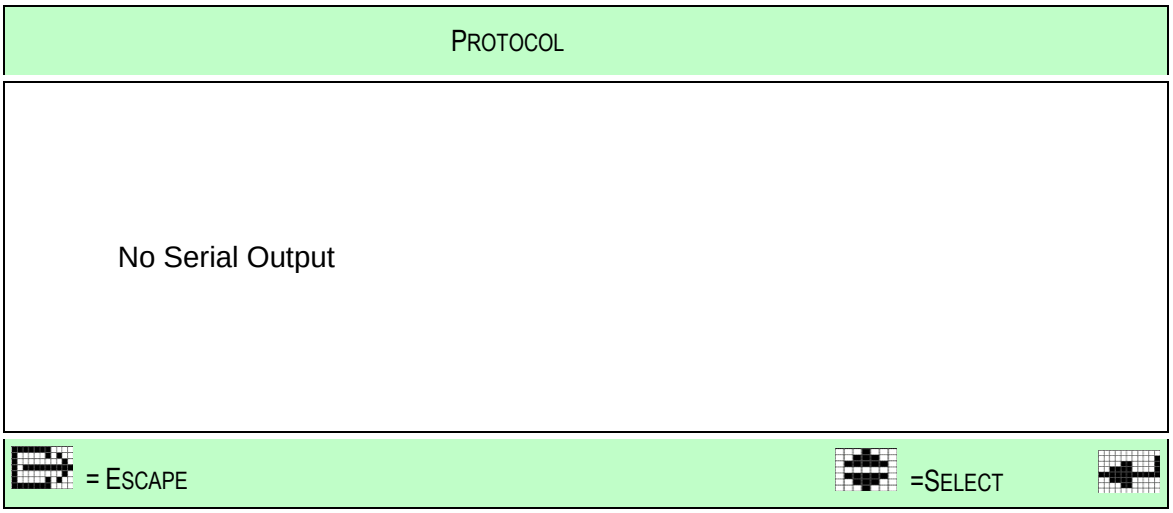


This function can be used to temporarily set a different sedimentation time for service or maintenance reasons.

Enter the required sedimentation time. Then press **[ENTER]** to save the new setting.

NOTE:
This setting is only active as long as the service chip card is present in the card reader. When the chip card is removed, the setting is automatically reset to 30 or 60 minutes according the selected method.

7.5.2.2.12. Menu Protocol

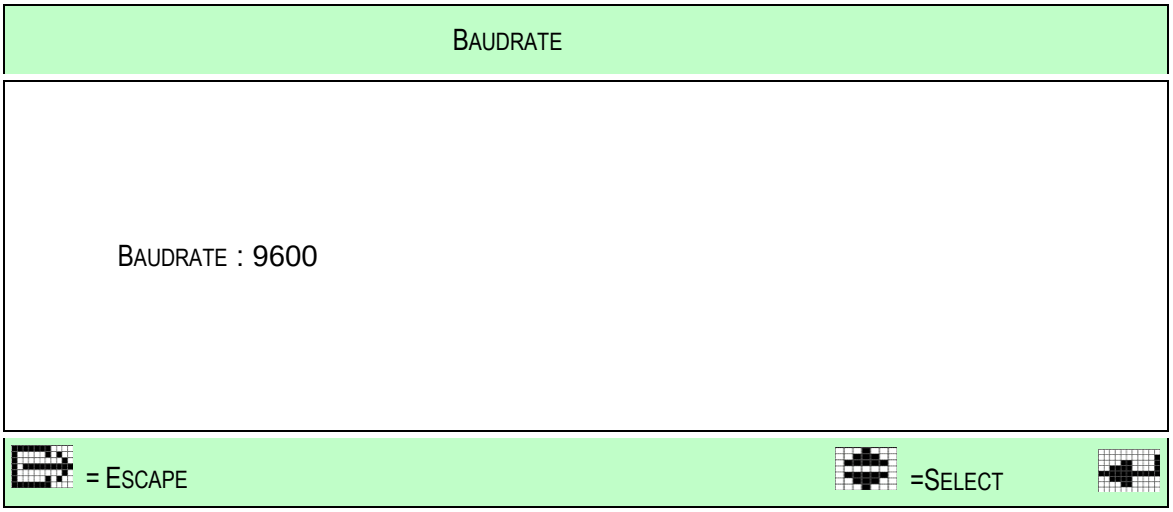


A protocol is a set of rules governing the communication and the transfer of data between machines, as in a computer system. Also a formal set of rules and procedures to be followed during a request for information before data is transferred between machines and computer systems.
The following protocols can be selected for data transfer to the Laboratory data processor computer.

1. No Serial output
2. ***MECHATRONICS-01 bidirectional*** (on page 155)
3. ***MECHATRONICS-02 unidirectional*** (on page 163)
4. ***Compact bidirectional*** (on page 151)
5. ***Compact unidirectional*** (on page 147)

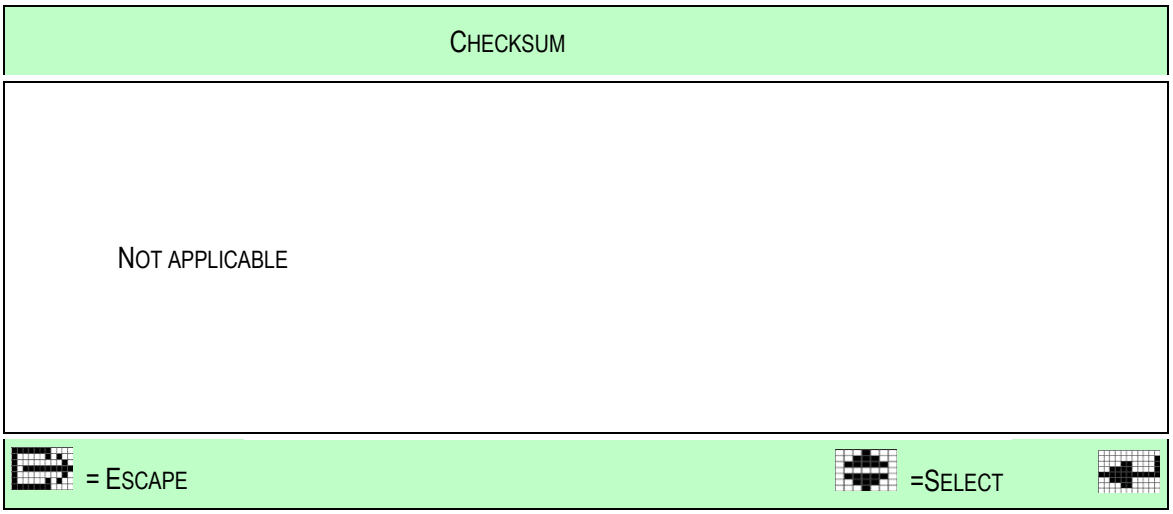
The protocol can be set in menu SETTINGS - PROTOCOL. After selecting a protocol, save the new settings by pressing the **[ENTER]** key.

7.5.2.2.13. Menu Baudrate



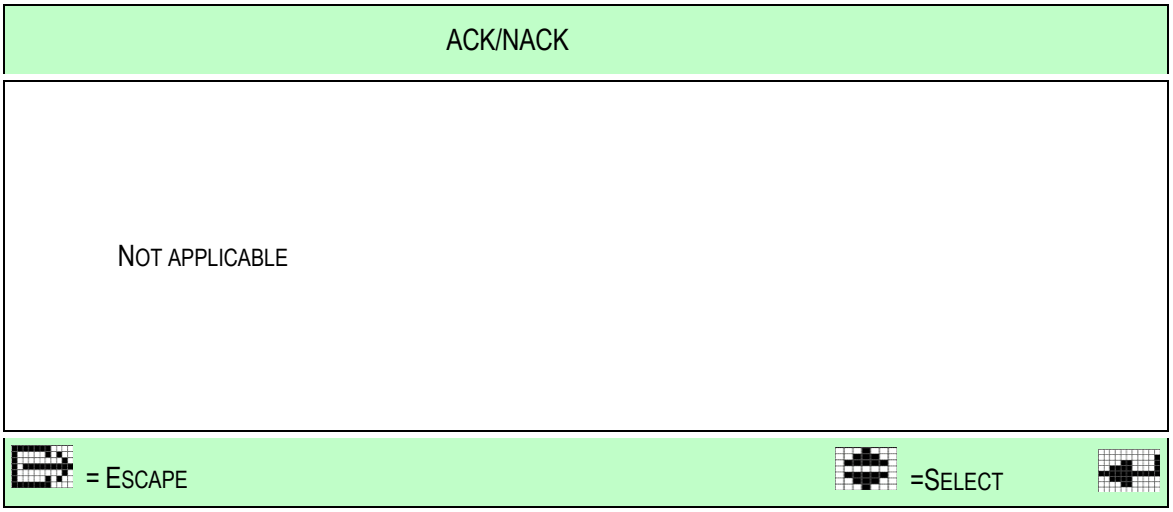
Use the **[ARROW DOWN]** or **[ARROW UP]** keys and select the required Baud rate (2400, 4800, 9600, 19200, 38400 (8-N-1).
Then press **[ENTER]** to save the new setting.

7.5.2.2.14. Menu Checksum



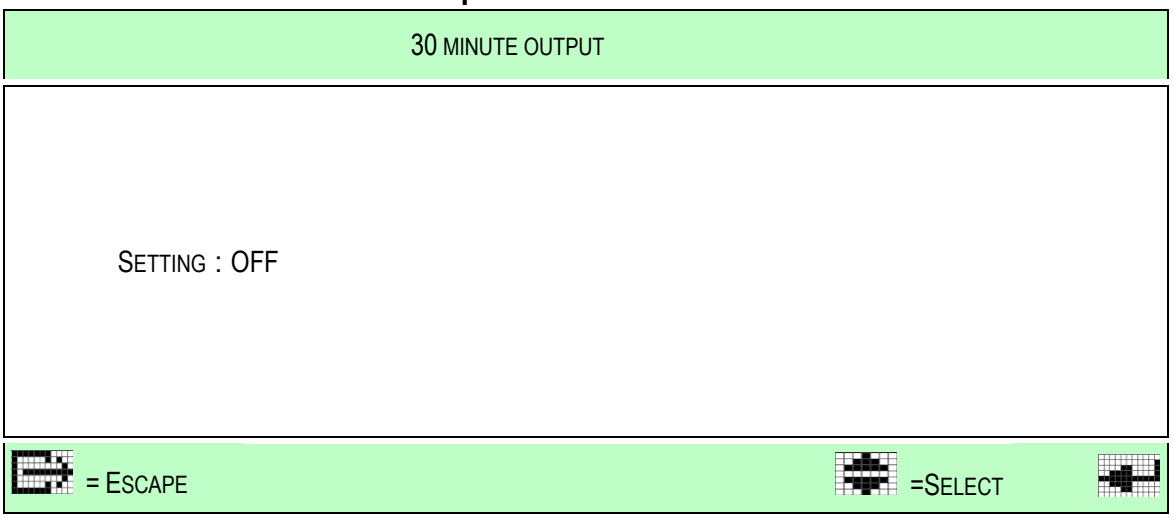
Note: This setting is only applicable if the output protocol is set to Compact unidirectional or Compact bidirectional.

7.5.2.2.15. Menu ACK/NACK



Note: This setting is only appliable if the output protocol is set to Compact unidirectional or Compact bidirectional.

7.5.2.2.16. Menu 30 minute output



Note: This setting is only appliable if the output protocol is set to Compact unidirectional or Compact bidirectional.

7.5.2.3. Menu 6 Service (Lab Supervisor)

		U	S	T
1	ERROR HISTORY	√	√	√
2	SOFTWARE VERSIONS	√	√	√
3	DISPLAY S/N	√	√	√
4				
5				
6				
7	NEXT		√	√

= ESCAPE =SELECT

Next submenu:

1	MOTOR CONTROL		√	√
2	VALVE CONTROL		√	√
3	SENSOR STATUS		√	√
4	MEASURE PIPET		√	√
5	READ BARCODE		√	√
6	REPLACE PIPET		√	√
7	NEXT		√	√

= ESCAPE

Next submenu:

1	EMPTY PIPET		√	√
2				
3				
4				
5				
6				
7				

= ESCAPE

7.5.2.3.1. Menu Motor control

1	WASTE M34	√	√
2	MEAS. M28	√	√
3	NOZZLE M29	√	√
4	FILLING M30	√	√
5	NEEDLE M31	√	√
6	GRIPPER M32	√	√
7	CAROUSEL M33	√	√

= ESCAPE =SELECT

These functions can be used to test the function of the motors or to move the associated unit to a particular position for service and maintenance reasons.

Select the required motor and use the **[ARROW DOWN]** or **[ARROW UP]** keys to switch the motor ON or OFF.

Warning:
These functions should only be used when there are no samples present that need to be processed.
Use these functions only if sufficient understanding of and experience with the instrument have been gained!

7.5.2.3.2. Menu Valve control

1	NOZ-NDL V23	√	√
2	DIL-CLN V23	√	√
3	VENTING V25	√	√
4	BLOOD V26	√	√
5	DILUTER V27	√	√

= ESCAPE =SELECT

These functions can be used to test the function of the valves for service and maintenance reasons.

Select the required valve and use the **[ARROW DOWN]** or **[ARROW UP]** keys to switch the valve ON or OFF.

Warning:
These functions should only be used when there are no samples present that need to be processed.
Use these functions only if sufficient understanding of and experience with the instrument have been gained!

7.5.2.3.3. Menu Sensor status

SENSOR STATUS

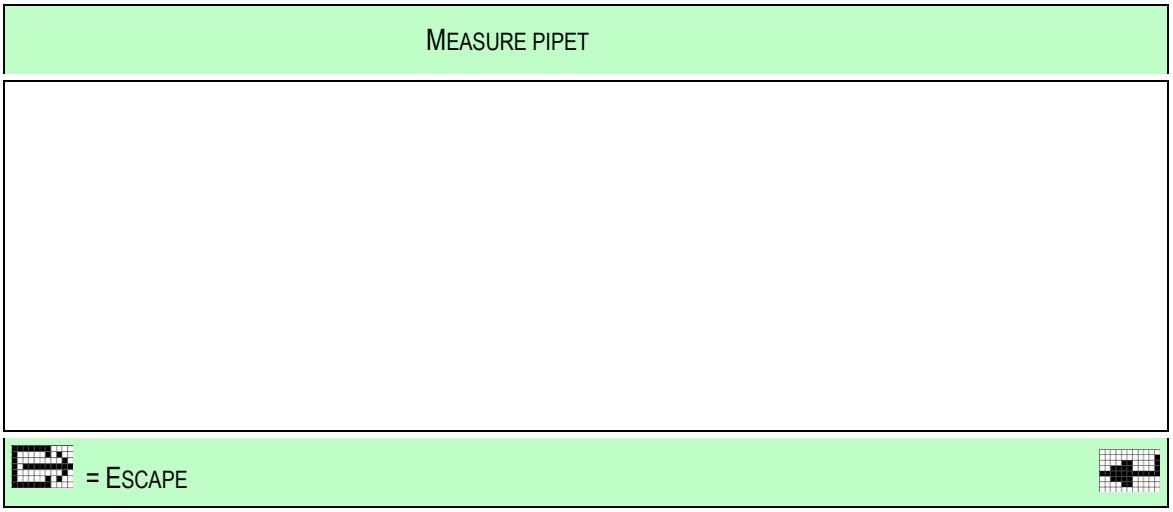
BLOOD DETEC. : 154
MEAS. HEAD: 40
TEMPERATURE: 20°C
POS. SENSOR : 235
WASTE SENSOR: 154

= ESCAPE

.

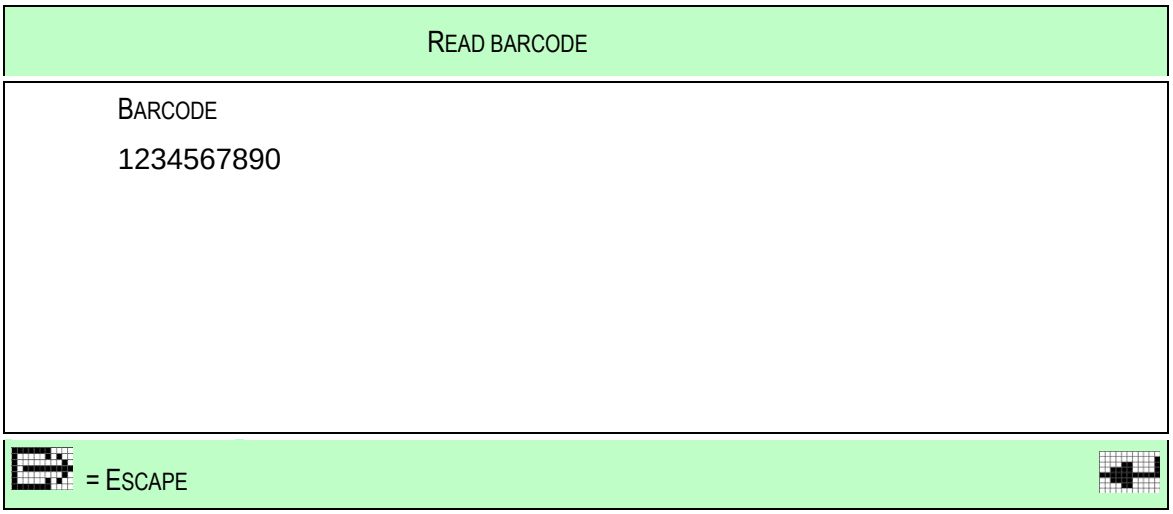
Note:
Waste sensor: Empty waste bottle > 120, Full waste bottle 87± 5, No waste bottle present < 30.

7.5.2.3.4. Menu Measure pipette



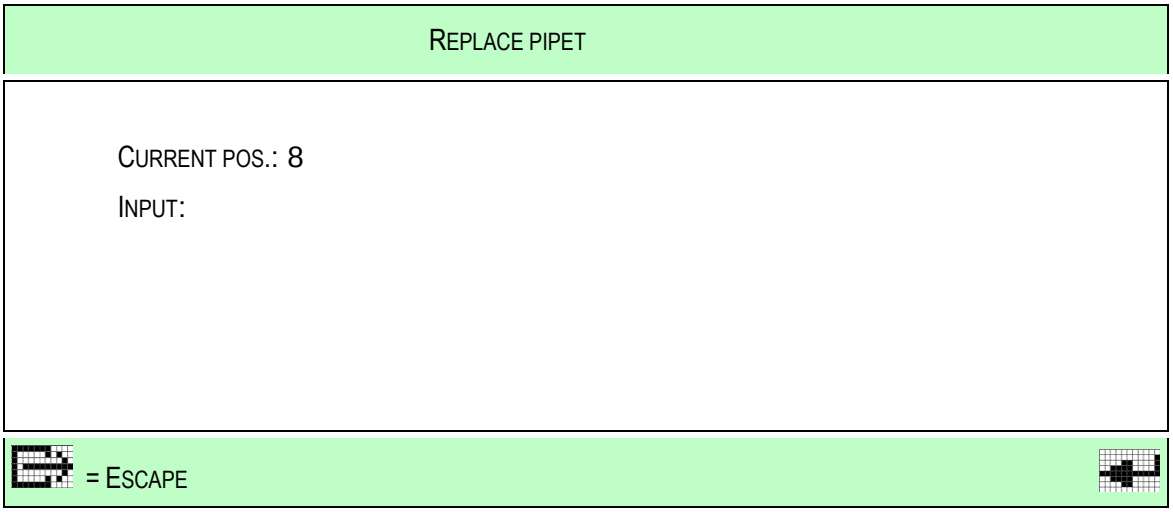
Press the **[ENTER]** key to measure the pipette that is currently in front of the measure unit. The result is printed on the build-in printer.

7.5.2.3.5. Menu Read barcode



To check the function of the barcode reader, place a sample tube with barcode in the needle unit and press the **[ENTER]** key. The detected barcode is displayed on the screen (in this example: 1234567890).

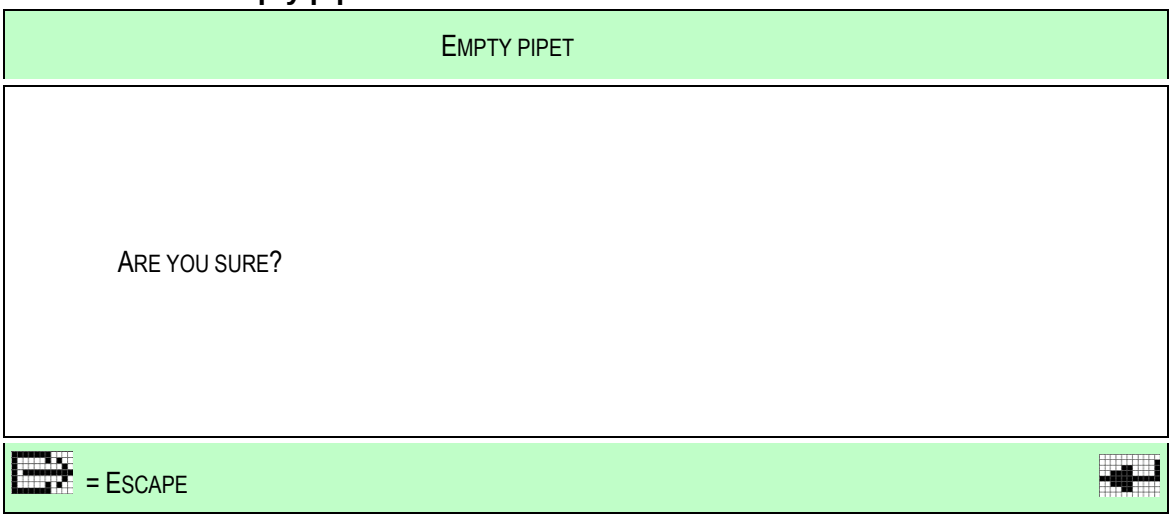
7.5.2.3.6. Menu Replace pipette



This function can be used to move a particular pipette to the door opening when the pipette needs to be replaced.

Enter the number of the pipette and press **[ENTER]**.

7.5.2.3.7. Menu Empty pipette



This function can be used to empty a pipette that may have remained filled due to an error condition.

The function is performed on the pipette that is currently at the nozzle position.
Press **[ENTER]** to confirm the selection and start the function.

NOTE:
To empty another pipette, use function CAROUSEL M33 in the menu MOTOR CONTROL to move the pipette to the nozzle position and then use function EMPTY PIPET.

7.5.3. Service menu section

Service functionality can be accessed with chip card types **S, I** and **T**.

Note: Software version Main 1.30, Slave I.O 1.15, Display 2.14 or higher.

7.5.3.1. Menu 5 Settings (Service)

		U	S	T
1	EN/DISABLE PIPET	√	√	√
2	PRINT SETTINGS	√	√	√
3				
4				
5				
6				
7	NEXT		√	√

= ESCAPE =SELECT

Next submenu:

1	30 MIN. METHOD		√	√
2	EDTA MODE		√	√
3	TEMPERATURE		√	√
4	T.CORR.		√	√
5			√	√
6	CAROUSEL POSITION		√	√
7	NEXT		√	√

= ESCAPE =SELECT

Next submenu:

1	DST (Daylight Saving Time)		√	√
2	RESULT AT LIMIT		√	√
3	PRINTER (RESULTS)		√	√
4	DATE / TIME		√	√
5	LANGUAGE		√	√
6	ESR TIME (MIN)		√	√
7	NEXT		√	√

= ESCAPE =SELECT

Next submenu:

1	PROTOCOL		√	√
2	BAUDRATE		√	√

3			√	√
4	CHECKSUM		√	√
5	ACK/NACK		√	√
6	30 MINUTE OUTPUT		√	√
√7	NEXT			√

= ESCAPE =SELECT

Next submenu:

1	SET PISTON POSITION			√
2	SET BLOOD SENSOR			√
3	SET WASTE SENSOR			√
4	BARCODE READER			√
5	MAX.NEEDLE CURRENT			√
6				
7	NEXT			√

= ESCAPE =SELECT

Next submenu:

1	FACTORY SETTINGS			√

= ESCAPE =SELECT

To return to the previous settings screen, press **[ESC]**.

To return directly to the Main menu, keep **[ESC]** pressed until the Main menu is displayed.

7.5.3.1.1. Menu Set piston position

SET PISTON POSITION

POSITION : 898 (898)

: MOVE PISTON

= ESCAPE

7.5.3.1.2. Menu Set blood sensor

SET BLOOD SENSOR

BLOOD DETEC. : 125

= ESCAPE

.

7.5.3.1.3. Menu Set waste sensor

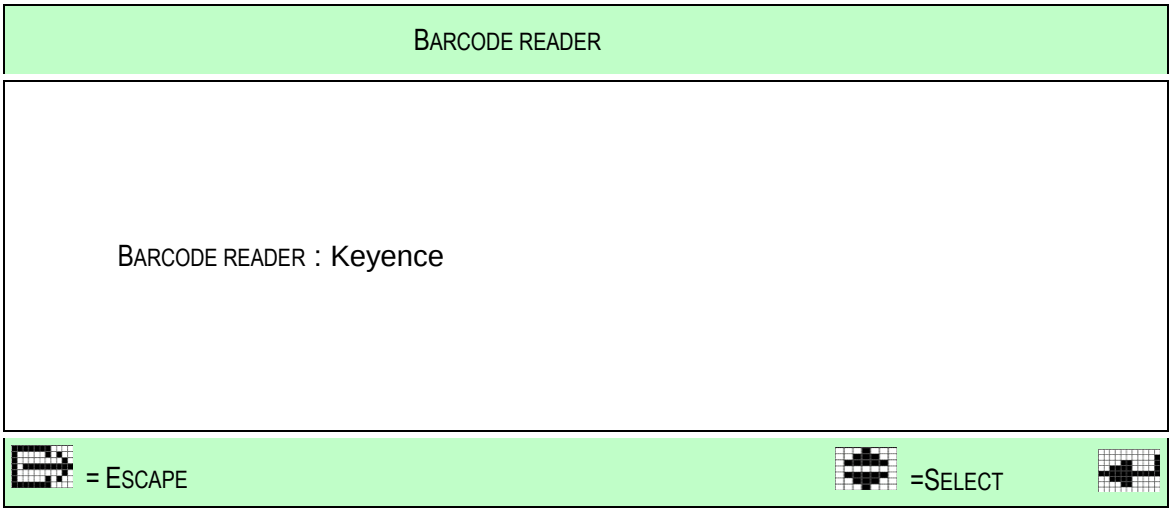
SET WASTE SENSOR

WASTE SENSOR : 125

= ESCAPE

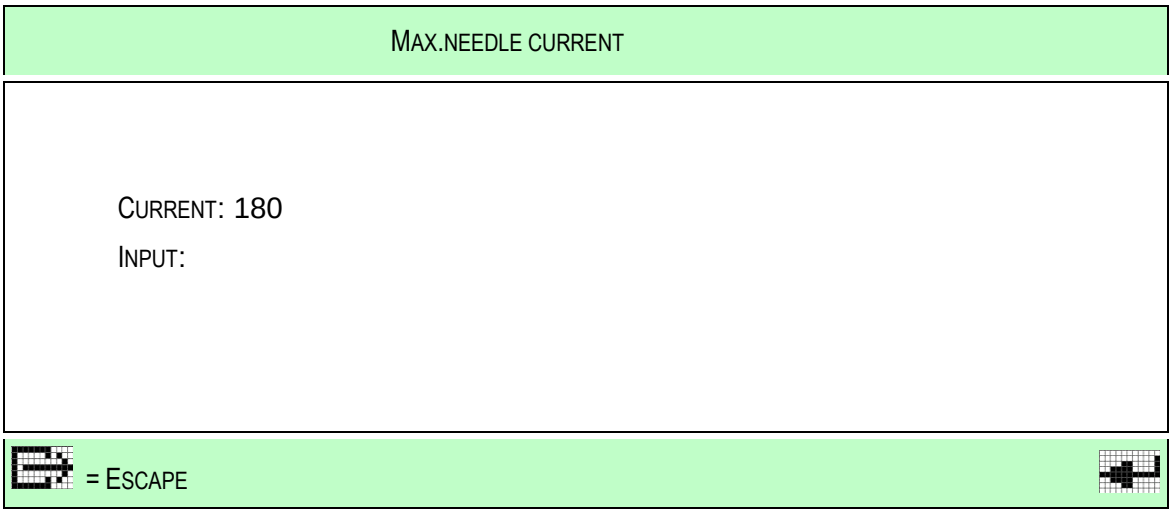
Note: Empty waste bottle >120, Full waste bottle 87± 5, No bottle <30

7.5.3.1.4. Menu Barcode reader

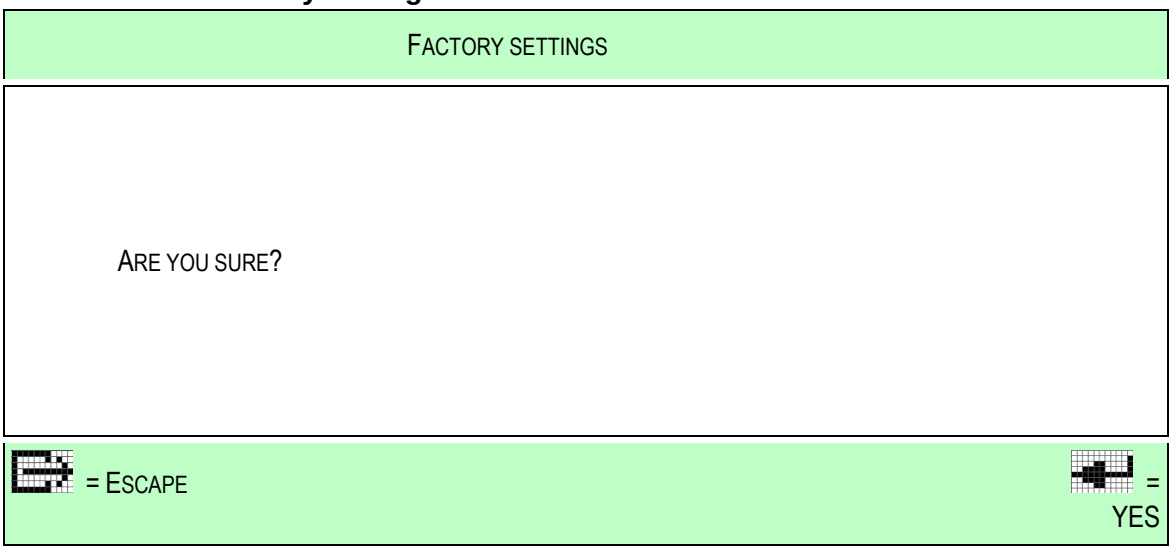


Make here the selection between the barcode reader type Opticon or Keyence.

7.5.3.1.5. Menu Max. needle current



7.5.3.1.6. Menu Factory settings



The StaRRsed Inversa is reset to the factory default settings.

7.5.3.2. Menu 6 Service

		U	S	T
1	ERROR HISTORY	√	√	√
2	SOFTWARE VERSIONS	√	√	√
3	DISPLAY S/N	√	√	√
4				
5				
6				
7	NEXT		√	√

= ESCAPE =SELECT

Next

1	MOTOR CONTROL		√	√
2	VALVE CONTROL		√	√
3	SENSOR STATUS		√	√
4	MEASURE PIPET		√	√
5	READ BARCODE		√	√
6	REPLACE PIPET		√	√
7	NEXT		√	√

= ESCAPE =SELECT

Next

1	EMPTY PIPET		√	√
2				
3				
4				
5				
6				
7				

= ESCAPE

.

7.5.3.2.1. Menu Clear error history

CLEAR ERROR HISTORY
ARE YOU SURE?
= ESCAPE =SELECT

7.5.3.3. Menu 7 Card & Credits

		U	S	T
1	LOAD CREDITS	√	√	√
2	READ SERVICE CARD	√	√	√
3	TRANSFER CREDITS			√
4	RESET SERV. COUNTER			√
5	SET D-FACTOR			√
= ESCAPE =SELECT				

7.5.3.3.1. Menu Load credits

1	LOAD CREDITS
2	READ SERVICE CARD

= ESCAPE =SELECT

Select 1 LOAD CREDITS. This function is used to load credit units from a credit chip card into the internal memory of the StaRRsed Inversa.

LOAD CREDITS

CONTINUE ?

= ESCAPE = YES

Press **[ENTER]** to start the function.

LOAD CREDITS

DO NOT REMOVE CARD

BUSY...(PLEASE WAIT)

= ESCAPE = YES

DONE ! ! !

TYPE: Q (**Note:** This is the code letter for the type of chip card)

SN: 123456789 (**Note:** This is the serial number of the chip card)

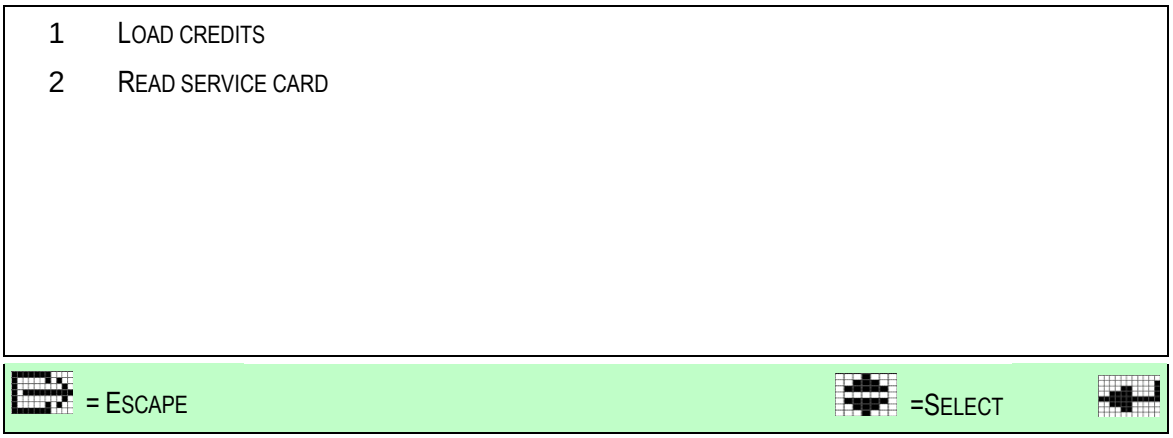
CREDITS: XXXXXXX

(**Note:** This is the total amount of available credit units in memory)

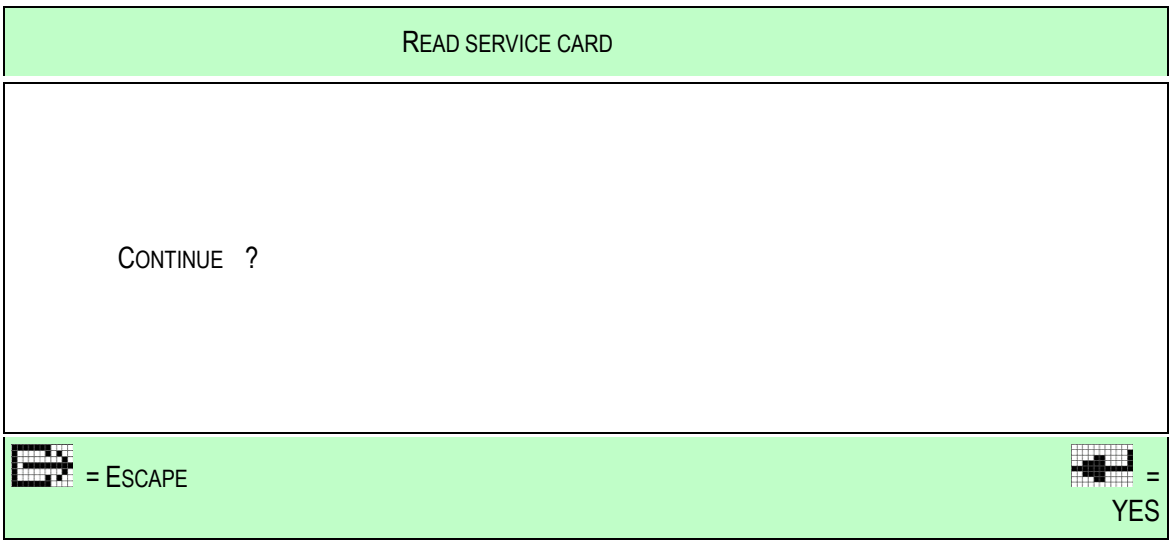
= ESCAPE

7.5.3.3.2. Menu Read service card

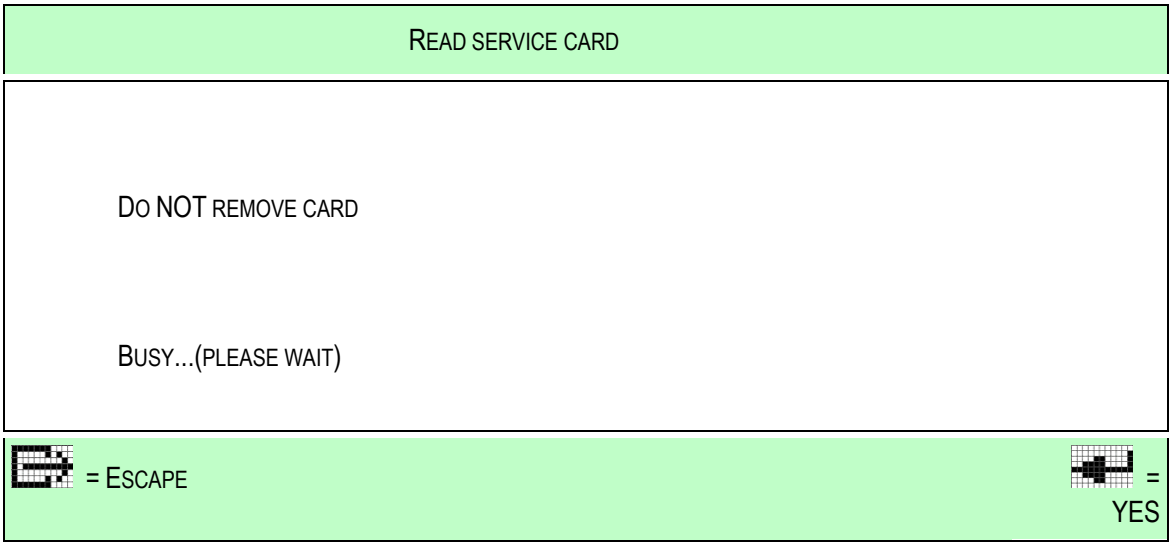
Make sure you insert a service chip card type in the chip card reader of the StaRRsed Inversa



Select 2 READ SERVICE CARD. This function is used to unlock the protected menus and functions.



Press **[ENTER]** to start the function.



READ SERVICE CARD

TYPE: S (**Note:** This is the code letter for the type of chip card)

SN:123456789 (**Note:** This is the serial number of the chip card)

PASSWORD: XXXX (**Note:** type the required password for this service chip card)

= ESCAPE

Enter the required password for the inserted type of service chip card and press **[ENTER]**. Wait until the display shows "CARD OK !".

8. QUICK START-UP

This section describes a quick start-up procedure and a general description of what to do before starting a large batch of samples to run through the system.

8.1. Power up sequence

Switch ON procedure:

- Switch the StaRRsed Inversa ON.
- Wait until the Main menu is visible on the display.
- The instrument is now ready.

8.2. Check list

The laboratory supervisor should check the following instrument settings and select the required options:

- Menu SETTINGS - 30 MIN. METHOD (Default is OFF)
- Menu SETTINGS - EDTA MODE (Default is ON)
- Menu SETTINGS - TCORR (temperature correction) (Default is ON)

NOTE:
A small hardware modification is necessary to switch between EDTA mode and Citrate mode. See work instruction WI-405 for details.

Check the following things before each large batch of samples:

1. Ensure that a chip card is present in the card reader. This may be any type of chip card.
2. Open the printer and check if enough paper is available. Replace if necessary.
3. Empty the waste container.
4. Check the liquid levels and refill the containers if necessary.

8.3. Printer paper replacement

When a red line appears across the length of the printout, the printer paper roll is approaching its end. The remaining paper is sufficient for ca. 24 printed reports. The red line marker is getting more intense as it comes closer to the end of the paper roll.

To open the printer, pull the handle at the top of the flap:

Insert a new paper roll as shown:

8.4. Liquid levels and reagents preparation

The liquid levels on the StaRRsed Inversa are automatically checked by sensors. To avoid level sensor alarms during routine operation, the liquid levels in the containers should also be checked visually every day.

NOTE:
Refill reagent as soon as possible when the level sensor alarm appears.

1. Reagents preparation.
   - Use only the reagent containers which are supplied with the StaRRsed Inversa.
   - To open the bulk reagent packages, remove the perforated flap from the cardboard box, pull the opening out of the box and fit the taps.
2. Fill up the containers with the reagents.
3. To remove the containers from the instrument, first pull the slider all the way up, then remove the bottle:

8.4.1. Diluent QRR 010931

Sodium citrate diluent is used for the dilution of undiluted EDTA samples and for the automatic rinsing of the sample system between samples.

- Approximately 5 ml Diluent is used for each sample cycle.

The on-board container for Diluent is a 1 liter plastic bottle. Fill the container with Diluent from the 5-liter bulk container (QRR 010931).

The solution should be discarded if it becomes turbid.
If the Diluent does become turbid, clean the Diluent container thoroughly with a 5% Na-hypochlorite solution. After cleaning, rinse the container thoroughly with de-ionized water. Before refilling, flush the Diluent bottle with a little Diluent from the bulk container.

NOTE:
The latest version of the Material Safety Data Sheet (MSDS) of the used reagents can be found on our web site ***www.mechatronics.nl*** (***http://www.mechatronics.nl***).

8.4.2. X-Clean QRR 010946

X-Clean is a ready-to-use cleaning solution that is used for the End-of-day wash. The solution removes residual proteins from the inner wall of the Westergren pipettes.

The on-board container for X-Clean is a 1 liter plastic bottle. Fill the container with X-Clean from the 5-liter bulk container (QRR 010946).

NOTE:
The latest version of the Material Safety Data Sheet (MSDS) of the used reagents can be found on our web site ***www.mechatronics.nl*** (***http://www.mechatronics.nl***).

8.5. Priming the fluid system

After starting the StaRRsed Inversa, a warning may appear on the screen stating that the last prime cycle was more than 12 hours ago. Press **[ENTER]** to start the priming cycle.

To start the priming manually, go to the Main menu and use the function PRIME. The priming cycle takes ca. 2 minutes to complete.

9. SAMPLE ROUTINE PROCEDURE

This section explains the necessary procedures for preparation and processing of blood samples on the StaRRsed Inversa.

9.1. Sample Mixing

To ensure that the blood cells are evenly dispersed throughout the sample, the sample tube must be mixed immediately before placing it in the sampling unit.
This can be done either manually or by using a sample tube mixer that inverts the tubes.
The sample tube must be fully inverted at least 7 times. Do not shake the sample.

NOTE: Ensure that the sample tube contains at least 2 ml of whole blood.

9.2. Placing sample tubes on the needle system

After mixing, insert the sample tube into the needle assembly with the cap downwards and the barcode label pointing towards the instrument.

9.2.1. Sample tubes with barcode

1. Start the SAMPLE MODE.
2. Push the **[START]** key.
3. Check that the scanned ID number appears on the display.
4. If the ID number does not appear on the display, the barcode could not be read:

1. Rotate the sample tube a little bit and push the **[START]** key again.
   or:
2. Enter the ID manually as described in the next section.

NOTE:
The sampling may not start immediately if a clean pipette is not yet available, but will start automatically when a clean pipette is available within 90 sec.

To prevent the aspiration of a not properly mixed sample, sampling will not start automatically when it takes longer than 90 sec. for a pipette to become available.
The operator must then remix the sample and push the **[START]** key again.

9.2.2. Sample tubes without barcode

If the sample tube has no barcode or the barcode can not be read, you can enter the sample ID manually.

1. Start the SAMPLE MODE.
2. Enter the ID number.
3. Push the **[START]** key.

NOTE:
The sampling may not start immediately if a clean pipette is not yet available, but will start automatically when a clean pipette is available within 90 sec.

To prevent the aspiration of a not properly mixed sample, sampling will not start automatically when it takes longer than 90 sec. for a pipette to become available.
The operator must then remix the sample and push the **[START]** key again.

9.3. Aspirating the sample

When a clean pipette is available, the needle assembly goes down and pushes the sample tube over the needles. The necessary blood volume is drawn from the sample tube into a tube (T3) until the blood sensor is triggered.

When the blood sensor is triggered, the piston of the Westergren pipette is pulled up to aspirate the sample into the pipette. During this fill motion the diluter syringe is driving the diluent via the nozzle into the blood stream.

NOTE:
If the StaRRsed Inversa is set to bidirectional communication with a HOST and ESR measurement is not required for this sample, the message "NO ESR!" is shown on the display. The sample will not be aspirated and may be removed from the needle unit.

9.4. Aborting the sample sequence

If a clean pipette is not available yet and sampling has not started yet, it is possible to abort the sample by pressing the **[CANCEL]** key.

NOTE:
As soon as the tube starts to move over the needle, it is not possible to cancel the aspiration sequence.

9.5. Automatic rinsing of the sample system

After each aspiration, the sample needle, sample tubes and fill nozzle are automatically washed with diluent.

9.6. Fill errors during sampling

After filling the sample into the pipette, the quality of the aspiration is checked by pre-measuring the pipette. The following parameters are checked:

- the column height
- the usage of diluent
- possible air bubbles

If there are any deviations, a beep will sound after the check.

10. TURN OFF

It is recommended to turn the StaRRsed Inversa off at the end of the day. Before the instrument is turned off, it is good practice to carry out the Daily maintenance or at least the End-of-day wash procedure. This will help to keep the instrument clean and almost free of bacterial growth for a period of days.

W A R N I N G!!!
Always be aware of the dangers of infection, especially during maintenance. Take the appropriate precautions.

10.1. End-of-day-wash procedure

The purpose of this function is to clean the inside of the pipettes from residue which may have accumulated over time.
In the Main Menu use the function END_OF_DAY WASH. This function takes ca. 30 minutes to complete.

All pipettes are automatically filled with X-Clean. When the last pipette was filled, the pipettes are emptied again.

The function may be aborted by pressing the **[CANCEL]** key.

NOTE:
If the function was aborted, the X-Clean may not have had enough opportunity to soak and clean the pipettes.

11. WASTE DISPOSAL

The waste container has a level sensor and as soon as the level sensor generates a waste error, the waste container must be emptied. The waste must be treated as potentially infectious (biohazardous) material and disposed of according to local regulations. Preferably, discard the complete waste container and replace it with a cleaned one.

Disclaimer: Check your local environment rules about discharging the waste.

11.1. Waste container

1. Unscrew the cap:

2. Lift the slider and take the waste container out of the compartment:

3. Close the container with the provided cap.

4. Install the empty container in the reversed order.

Warning:
The waste must be treated as potentially infectious (biohazardous) material.

NOTE:
If you are re-cycling the waste container, make sure that it is bleached and rinsed thoroughly.

12. REPORTING

The StaRRsed Inversa is able to transmit different types of reports to the serial output port. In **Menu 5** Settings (Lab Supervisor) the following options are selectable.

30 MIN. METHOD	(on/off)
CHECKSUM	(on/off)
ACK/NACK	(on/off)
30 MINUTE OUTPUT	(on/off)

[CHECKSUM] is select ON , at the end of the string an extra byte is added. Checksum output string: 1 byte checksum = 256 (modulo 256 (ASCII string sum)). This output is also known as the advanced output.

[ACK/NACK] is select ON **;** a confirmation is expected from the host computer after serial transmission. After receiving a **"Nack**", StaRRsed sends the data again (maximum two times). An **"Ack"** will let the StaRRsed carry on immediately.
If "Ack/Nack" is not received, the Instrument carries on after a pause of 1 second between the transitions. **("ACK"**= Acknowledge, **"NACK"**= Not acknowledge.)

See also ***Appendix - String format for StaRRsed*** (on page 147).

[30 MINUTE OUTPUT] is ON the format of the report is changed independent of the selection of the status of checksum or ACK/NACK.

[30 METHOD] is ON the ESR time automatically switches to 30 minutes and cannot be changed manually. The actual measured [30-MINUTE] result will only be printed and sent to the host computer if 30 MINUTE OUTPUT is set to '**on**' as well. If this method is switched **OFF** the ESR time automatically switches to 60 minutes. The converted Westergren standard (60 minute result) is sent to the printer and to the serial port.

The StaRRsed Inversa performs the **ESR after 30 minutes** (instead of 60 minutes) and converts this value to a 60 minute **Westergren** standard. The method has the advantage that sample results become available after 30 minutes to the operator, however this method is not according to the Westergren method and results may deviate from the original Westergren results. For conversion to a standard Westergren, a table is used which correlates a **30-minute** ESR to a **60**-minute **ESR** result.

The method has been proposed and evaluated by Mr. Richard Rogers of the Royal Berkshire Hospital, Reading (U.K.). (See Medical Laboratory World, April 1994.)

Note: It is not recommended to use the 30-minute method on pre-citrated sample tubes.

12.1. Protocols

A protocol is a set of rules governing the communication and the transfer of data between machines, as in a computer system. Also a formal set of rules and procedures to be followed during a request for information before data is transferred between machines and computer systems.
The following protocols can be selected for data transfer to the Laboratory data processor computer.

1. No Serial output
2. ***MECHATRONICS-01 bidirectional*** (on page 155)
3. ***MECHATRONICS-02 unidirectional*** (on page 163)
4. ***Compact bidirectional*** (on page 151)
5. ***Compact unidirectional*** (on page 147)

The protocol can be set in menu SETTINGS - PROTOCOL. After selecting a protocol, save the new settings by pressing the **[ENTER]** key.

12.2. Result Printout

The results of the ESR measurements are send to the built-in printer and printed on thermal paper.

The layout of the report depends on the selection of the 60- or 30-minute method.

NOTE:
Thermal paper is sensitive to light and printouts will start to fade after several weeks. If you need to retain the printed reports for future reference, store the printouts in a cool, dark place or make copies on a regular copy machine.

NOTE:
The descriptions "Line 1" to "Line D" in the following subsections are only for reference within this documentation. These descriptions do not appear on the printout.
Which lines are actually displayed on the printout depends on the instrument settings and the printed result.

12.2.1. Report 60-Minute mode

	Column 1	Column 2	Column 3	Column 4
Line 1	ID		1234567890	
Line 2	ESR T. corr		75	mm/1H
Line 3	ESR 60:		84	mm/1H
Line A	Aspect		Clear	
Line B	EDTA:	ON	ESR time	60
Line C	15-03-10	13:01	23 ºC	P15
Line D				

Patient number. 1234567890

Line 1	ID	1234567890	

60-minute ESR result in millimeters, corrected for **18**°C. (only in use if temperature correction is active).

Line 2	ESR T. corr	75	mm/1H

Not corrected 60-minute ESR result.

Line 3	ESR 60:	84	mm/1H

Aspect (clear, hazy).

Line A	Aspect	Clear	

EDTA mode is On or OFF

Line B	EDTA:	ON	ESR time	60

ESR TIME: Actual sedimentation time in minutes.

Line C	15-03-10	13:01	22 ºC	P15
	The present date	Present time	Present temperature	Pipette number, in this example pipette 15

Line D is used for error and warning messages and printed in reversed colours.

12.2.2. Report 30 Minute mode

	Column 1	Column 2	Column 3	Column 4
Line 1	ID		1234567890	
Line 2	ESR T. corr		75	mm/1h
Line 3	ESR 60:		84	mm/1h
Line 4	ESR 30:		42	mm/½h
Line A	Aspect		Clear	
Line B	EDTA:	ON	ESR time	30
Line E	15-03-10	13:01	23 ºC	P15
Line D				

Patient number.

Line 1	ID	1234567890	

60-minute ESR result in millimeters, corrected for **18**°C. (only in use if temperature correction is active).

Line 2	ESR T. corr	75	mm/1H

Not corrected 60-minute ESR result.

Line 3	ESR 60:	84	mm/1h

Not corrected 30-minute ESR result (only in use if 30 minute mode is active).

Line 4	ESR 30:	42	mm/½h

Aspect (clear, hazy).

Line A	Aspect	Clear

EDTA mode is On or OFF

Line B	EDTA:	ON	ESR time	30

ESR TIME: Actual sedimentation time in minutes.

Line C	15-03-10	13:01	22 ºC	P15
	The present date	Present time	Present temperature	Pipette number, in this example pipette 15

Line D is used for error and warning messages and printed in reversed colours.

12.2.3. Analyser ERROR

Error messages can be found on the printout at the bottom line in reversed colours.
All other lines of the report are removed accept the line with patient ID, and line B and C.

If errors are found during the measurement, the StaRRsed Inversa will give an audible alarm.

12.2.3.1. Analyzers Error code messages

Analyzers "ERROR" code messages

This code appears in the "sample data record" at column 10.
The following codes are defined:

0	NO ERRORS	
1	No cells/plasma found	ERROR
2	ESR Probably > 140 mm	ERROR
3	Too many borders found	ERROR
4	Column height <nnn>	WARNING
5	Measure error	WARNING
6	Bubbles on top	WARNING
7	Limit error	ERROR

12.2.3.2.Explanation of the error messages

No cells/plasma found. **(**ERROR**)**
No contents could be detected in the pipette.

ESR Probably > 140 mm. **(**ERROR**)**
Extremely high ESR value.

Too many borders found. **(**ERROR**)**
More than three borders found, possibly air bubbles. (See Section Trouble shooting Air bubbles).

Column height <nnn>. **(**WARNING**)**
Column height must be between 180 and 210mm. <nnn> = the actual column height.

Measure error. **(**WARNING**)**
The down count is not equal to the up count from the measure head.

Bubbles on top. **(**WARNING**)**
Air bubbles on top of the ESR.

Limit error **(**ERROR**)**
One of the following limits are out of range.

- The ESR time
- The column height
- Dilution errors

12.2.4. Results at limit errors

When this option is set to YES and a limit error occurs, results will be printed/send to the LIMS.

When this option is set to NO and a limit error occurs, the fields for *30 min ESR, 60 min ESR* and the *temperature corrected ESR* are filled with spaces and thus results are not printed/send to LIMS.

The error message in the error field (column 10) indicates that at least one of the the limits (ESR time, dilution rate or column height) has been exceeded.

Together with the sedimentation time and dilution rate (which are still printed at the usual position), the operator can see what caused the error and may or may not use the ESR values which are preserved in the error message.

Description of the error message **L_err(hhh/www/ttt/ccc)** :

- **L_err** means it is a "limit error"
- **hhh** is the 30 minutes ESR
- **www** is the 60 minute ESR
- **ttt** is the temperature corrected 60 minute result
- **ccc** is the column height

Example of a limit error message:

- L_err(42/ 84/ 75/200) means 42 mm in the 30 minute method and temperature correction 75 with a correct column height.
- L_err(---/ 84/ 75/200) means 84 mm in the 60 minute method and temperature correction 75 with a correct column height.

12.2.5. Reporting range

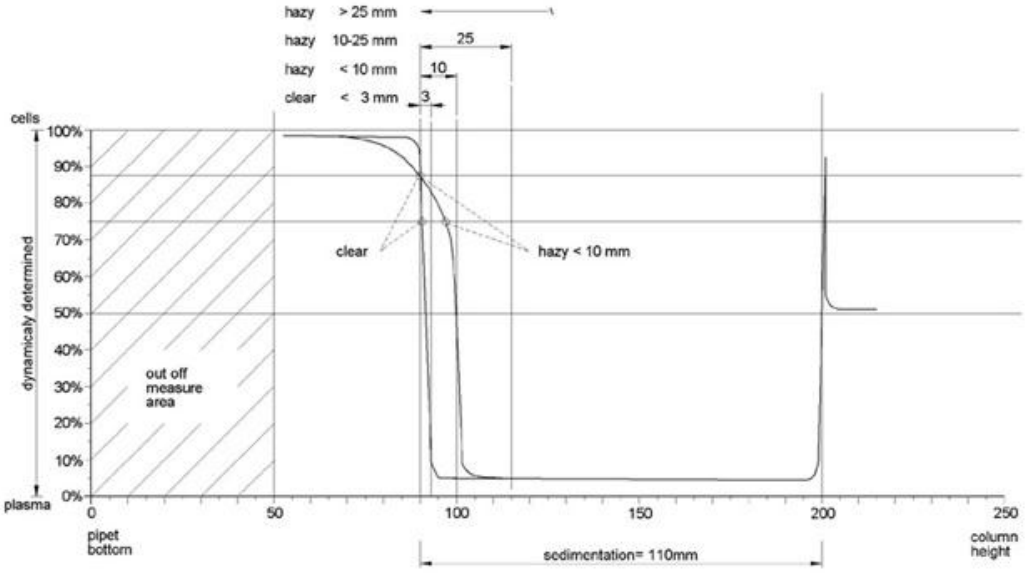
The reporting range in the lines 2, 3 and 4 are in millimeters. The start of the measure range is at the top of the meniscus down to 140 mm. If the detection of cells/plasma is over 140 mm then the report will be >140.

12.2.6. Aspect Hazy

The automatic reading of the Westergren sedimentation pipettes is carried out by moving an optical sensor along the pipettes. While the sensor is moving, a reading is made every 0.25 mm. The sensor is reading the absorption of infra red light through the Westergren pipette filled with blood. From these readings, values at a number of absorption levels are determined. All absorption figures are relative to the darkest and lightest reading (darkest = 100 % and the lightest = 0 % absorption respectively).

By definition the levels are:

87.5%	Cells/ plasma separation
75.0%	Hazy detection
50.0%	Meniscus detection



Graphic showing typical absorption values of a sample

The 'sedimentation' value is the distance in millimeters between the cells/plasma level (87.5% absorption) and the meniscus. If there ins no haze, the absorption drops quickly to a value below the 75% level. If the distance between the 87.5% and the 75% level is less then 3mm, the report will state 'CLEAR'. If the distance between 87.5% and 75% level is more than 3mm then the report will state 'HAZY'.

Depending on the length of the 'hazy' area, three classes of 'hazyness' are reported,

Length of area		**Reported class**	
Hazy area	>25 mm	Hazy	>25 mm
Hazy area	>10 mm <25 mm	Hazy	<25 mm
Hazy area	>3 mm < 10 mm	Hazy	<10 mm
Hazy area	< 3 mm	CLEAR	<3 mm

Hazy reports are shown when the change from the hazy level to the cell/plasma separation level occurs not within a given distance. The following bands are reported in the aspect column of (number 5)

12.2.6.1. Analyser "HAZY" code messages

This code appears in the "sample data record" at line A.

The following 4 codes are defined:

0	Sample is clear.
1	Sample is Hazy < 10
2	Sample is Hazy < 25
3	Sample is Hazy > 25

13. INVERSA SYSTEM MESSAGES

13.1. System messages

During normal operation the following "**system messages**" may occur:

1. Waiting tube.
   - If a filled pipette is at the measuring position before the elapsed time has finished and the operator is ready to fill the next pipette, the waiting tube message will be displayed.
   - To continue the sample loading sequence the operator must wait until the pipette at the measuring position has been measured.

2. Printer failure
   - Check paper quantity.
   - Note: data will be stored in the buffer and can be printed afterwards.

3. Reagents level empty message
   - All reagent bottles have level detectors; the display shows an error that indicates which reagent bottle(s) is (are) empty.
   - Prepare new reagent as described in section Quick start-up.

4. Waste bottle full message or No waste bottle message
   - The waste container also has a level detector. If a waste error is shown on the display, the StaRRsed Inversa will stop filling and cleaning pipettes until a new or empty container has been installed.
   - Empty the waste container and press **[ESC]** to clear the error.

14. DATA MANAGEMENT

All data in the StaRRsed Inversa is stored in a battery back-up memory. Therefore important data is kept, irrespective of a power failure or if the instrument is unintentionally turned off.

When switched on, the StaRRsed Inversa will check its memory and if there are filled pipettes on the Instrument these samples will be processed. If the sample time has been exceeded, the sample result or an error message will be printed in the report printout, based on the "Result at Limit Error" settings.

14.1. Power failure

If a power failure occurs it is recommended that the StaRRsed Inversa is switched **OFF** by the power switch. When the power returns, the Instrument can be switched **ON**. After the standard start-up process the StaRRsed Inversa will continue to process the remaining samples.

If a power failure occurs, the sedimentation time (60 or 30 min.) may be exceeded. However, the actual sedimentation time is reported to the printer and RS232 and therefore can be checked.

14.2. RS232 serial output

The StaRRsed Inversa is equipped with a serial port, which can be connected to any laboratory host computer system or PC. The data sent by the StaRRsed Inversa to the printer can also be sent to a host computer or PC for further processing.

14.3. Specifications for the RS232 port

RS232 Serial data transmission.
Baud rate can be set from **2400** to **38400** baud. Transmission protocol is default setting: **8** bit data, **1** stop bit, and **no** parity. To change the baud rate go to

For more detailed information on the Serial connection see ***Appendix - RS-232 (9 pins sub D female) hardware connector*** (on page 168)

15. MAINTENANCE

The **StaRRsed Inversa** is an analyzer that operates with considerable amounts of whole blood virtually undiluted, and stores it in a pipette for one hour. For this reason instrument maintenance is of the utmost importance.

To maintain the maximum reliability of the instrument, the maintenance procedures must be strictly followed. All procedures are based on a number of samples.

Maintenance levels	Work instruction
Daily (on page 121)	***WI-400 Daily*** (on page 172)
Weekly (on page 121)	***WI-401 Weekly*** (on page 173)
Level 4 maintenance (on page 122)	***WI-404 Level 4 maintenance*** (on page 179)
Level 3 Maintenance	***WI-403 Level 3 maintenance*** (on page 177)
Level 2 maintenance	***WI-402 Level 2 maintenance*** (on page 175)
Level 1 maintenance	not available yet

WARNING!!!
Always be aware of the danger of infection, especially during maintenance. Take appropriate precautions. There is blood involved and therefore a **BIO HAZARD**

15.1. Daily

The purpose of the daily maintenance is to keep the instrument clean and contamination as low as possible.

See work instruction ***WI-400 Daily*** (on page 172) for a step-by-step procedure.

15.2. Weekly

The purpose of the weekly maintenance is to carry out the daily maintenance and additionally check for worn components.

See work instruction ***WI-401 Weekly*** (on page 173) for a step-by-step procedure.

15.3. Level 4 maintenance

The purpose of level 4 maintenance is to carry out the daily and the weekly maintenance.

Check the waste pump tube condition. Replace the tube if it appears worn or leaking

See work instruction ***WI-402 Level 4 maintenance*** (on page 175) for a step-by-step procedure.

15.4. Level 3 maintenance

15.5. Level 2 maintenance

15.6. Level 1 maintenance

Not available yet.

16. TROUBLE SHOOTING

Occasionally small faults may cause major problems. This chapter may help to solve the most common faults and explain why a specific problem occurs.
A lot of the problems or errors are due to a lack of maintenance. Remember that this instrument operates with a considerable amount of whole blood, virtually undiluted, stores it in a pipette for one hour and then cleans pipettes for re-use. Therefore, it is important to keep to the maintenance schedules. It is recommended that trained service personnel checks and applies service to the instrument at least once a year.

16.1. General error procedure

Whenever an error occurs, follow the instructions given in the Error list. If no instructions are given, follow this general procedure:

1. Clear the error by pressing the **[ESC]** key.
2. When the error is not cleared or the error occurs again:
3. Switch the StaRRsed Inversa OFF.
4. Switch the StaRRsed Inversa ON.

When the error occurs again, switch OFF all units and call for service.

16.2. Reagents

Check the expire dates of the reagents regularly. Do not use the reagents if expired.

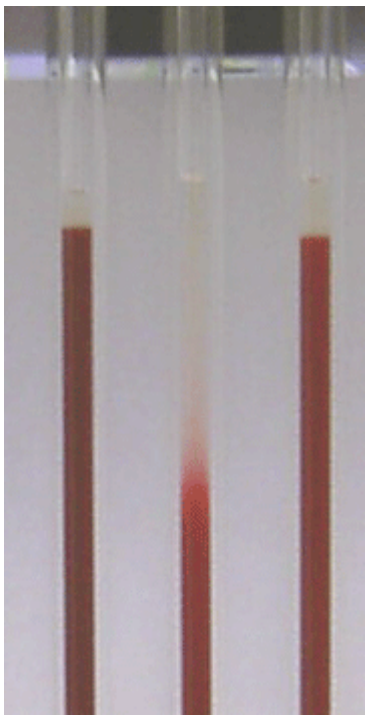
Note: If expired reagent has been used accidentally, the results obtained with these reagents may only be used, when the expire date was not exceeded more than 30 days.

Diluent is sensitive for bacterial growth. The solution should be discarded if it becomes turbid or infected. When using the small onboard containers, clean the Diluent container thoroughly with 10% Na-hypochlorite. Make sure that the container has been thoroughly rinsed after cleaning.

16.3. Hazy reports

"Hazy" reports are usually caused by a build-up of proteins on the inner wall of the pipettes. Another cause is growth of micro organisms in the diluter system. It is extremely important that the system is kept clean.

First run an extra END_OF_DAY WASH, then check after a day's run if haziness is decreased. When there are still many reports, it is recommended to fill the diluter system with a 5% sodium hypochlorite solution.



A picture example of haziness

16.4. Leaking pipettes

Pipettes may be leaking if the plunger tip is worn.

16.4.1. Column height

When there is a column height error detected the software assumes that the pipettes is leaking and disables the future use of this pipette.

16.4.2. Disabling a pipette

If a pipette is leaking only slightly, this may not be detected by the instrument. Individual pipettes can be disabled manually for further use until they can be replaced:

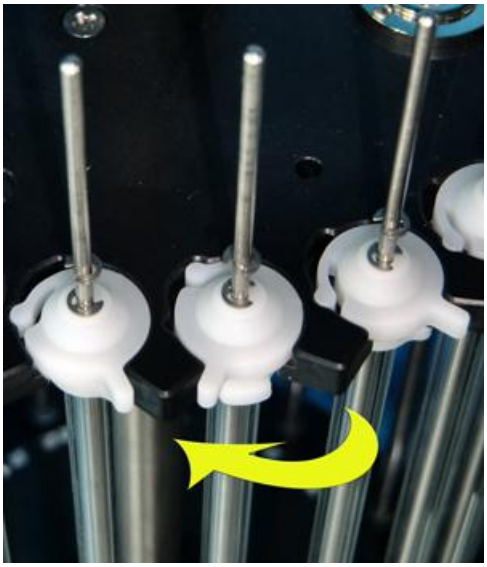
- Note the number of the leaking pipette.
- Wait until the pipette is measured and empty.
- Go to Menu SETTINGS - EN/DISABLE PIPET and ***follow the instructions*** (on page 54).

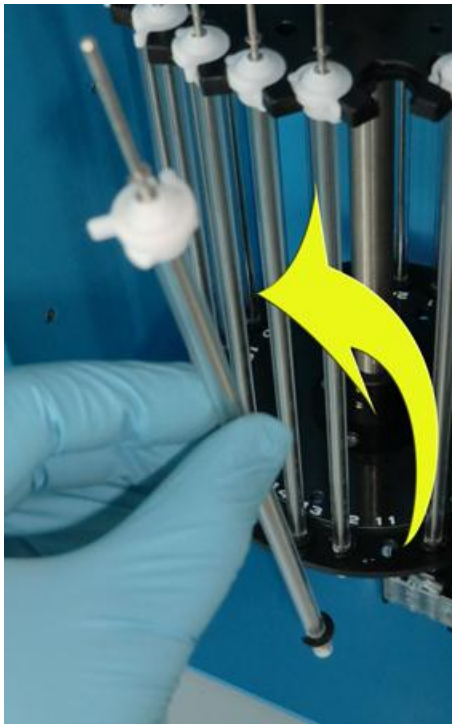
16.4.3. Replacing a pipette

NOTE: Chip card type **S** is required !

NOTE:
Make sure that all pipettes are empty and do not need to be measured.

- Go to Menu SERVICE - REPLACE PIPET.
- Enter the number of the pipette to replace and press **[ENTER]**. The pipette is turned to the door opening.
- Open the pipette cap and lift the pipette out. Install the new pipette in the reversed order.

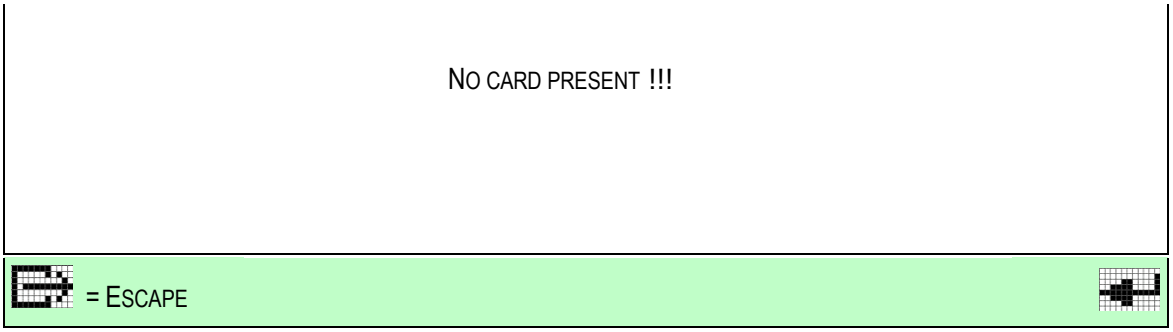




16.5. Sampling not allowed now

If no chip card is inserted in the card reader and the sample mode is started by pressing 1 Sample mode, the following screen is shown:

Sample mode
: NOT ALLOWED NOW !!!



- Press **[ESC]** to return to the main menu.
- Insert **Q** chip card or **A** to **E** chip card.
- Press 1 Sample mode.

17. APPENDIX FOR STARRSED INVERSA

Appendix section

Appendix - Error list StaRRsed Inversa

Error No.	Description	Action	Remark / Possible cause
1	Unknown function. (Not programmed)		Function is under construction.
2	Unknown menu. (Not programmed)		Menu is under construction.
3	Carrousel position error.	Set correct rinse position.	Sensor value does not match with the value stored in memory. • Set correct carrousel position and/or do a "Learn positions". • Carrousel Position sensor malfunction.
4	Checksum error. Default RAM settings are loaded	Check settings.	Calculated checksum does not match with the checksum stored in RAM. • Empty battery on main board. • RTC (DS1302) malfunction.
5	(Number not assigned)		
6	Internal I2C communication error.		If this error occurs repeatedly, contact local service engineer.
7	Waste bottle full.	Empty waste bottle and clear error.	• Level sensor malfunction.
8	Warning: Diluent bottle empty.	Fill Diluent bottle.	• Level sensor malfunction.
9	Warning: Cleaning Solution bottle empty.	Fill Cleaning Solution bottle.	• Level sensor malfunction.
10	(Number not assigned)		
11	Unknown status in cleaning routine.	Reset the instrument	If this error occurs repeatedly, contact local service engineer.
12	Fatal error in cleaning routine.	Reset the instrument	If this error occurs repeatedly, contact local service engineer.
13	Error in cleaning routine -> aborted.		If this error occurs repeatedly, contact local service engineer.
14	(Number not assigned)		
15	Unknown status in fill routine.	Reset the instrument	If this error occurs repeatedly, contact local service engineer.
16	Fatal error in fill routine.	Reset the instrument	If this error occurs repeatedly, contact local service engineer.

17	Fill timeout.	Check sample.	No blood detected within x seconds. • Empty sample tube. • Blood detection sensor malfunction.
18	Error in fill routine -> aborted.		If this error occurs repeatedly, contact local service engineer.
19	No sample tube detected.	Place sample tube.	• Needle sensors malfunction.
20	(Number not assigned)		

21	Fill sensor error.	Check blood detection sensor.	• Blood detection sensor out of range. • Check for drops of liquid.
22	(Number not assigned)		
23	(Number not assigned)		
24	(Number not assigned)		
25	Filling motor could not go to home position. Gripper is closed.		• Gripper must be open. • Gripper sensors malfunction.
26	Not allowed to start Filling motor. Carrousel is not at a defined position.		• Carrousel home sensor malfunction.
27	Filling motor could not go down all the way. Gripper is closed.		• Gripper must be open. • Gripper sensors malfunction.
28	Filling motor pulse disk error.		No pulses were detected. Position of filling motor unknown. • Pulse disk malfunction. • Filling motor jammed or malfunction.
29	(Number not assigned)		
30	(Number not assigned)		
31	Carrousel could not turn. Gripper is closed.		• Gripper must be open. • Gripper sensors malfunction.
32	Carrousel could not turn. Measure head not at home position.		• Measuring motor home sensor malfunction.
33	Carrousel could not turn. Nozzle not at home position.		• Nozzle sensors malfunction.
34	(Number not assigned)		

35	Not possible to open or close gripper. Carrousel is not at a defined position.		• Carrousel home sensor malfunction.
36	Not possible to move the measure head. Carrousel is not at a defined position.		• Carrousel home sensor malfunction.
37	Not possible to move Nozzle up or down. Carrousel is not at a defined position.		• Carrousel home sensor malfunction.
38	Needle current too high.		• Sample tube placed incorrectly. • Needle motor malfunction. • Needle motor jammed.
39	(Number not assigned)		
40	Unknown status in measure routine.		If this error occurs repeatedly, contact local service engineer.

41	It is not allowed to measure the pipette.		Pipette is filled with a sample but not ready for measurement.
42	Error in measure routine -> aborted.		If this error occurs repeatedly, contact local service engineer.
43	(Number not assigned)		
44	(Number not assigned)		
45	Unknown status in rotate routine.		If this error occurs repeatedly, contact local service engineer.
46	Error in rotate routine -> aborted.		If this error occurs repeatedly, contact local service engineer.
47	(Number not assigned)		
48	(Number not assigned)		
49	(Number not assigned)		
50	Unknown status in motor initialization routine.	Reset the instrument	If this error occurs repeatedly, contact local service engineer.
51	Error in motor initialization routine -> aborted.	Reset the instrument	If this error occurs repeatedly, contact local service engineer.
52	Filling motor timeout.		• Filling motor malfunction. • Filling motor jammed.

53	Needle motor timeout.		• Needle motor or sensor malfunction. • Needle motor jammed.
54	Carrousel motor timeout.		• Carrousel motor or sensor malfunction. • Carrousel jammed.
55	Gripper motor timeout.		• Gripper motor or sensor malfunction. • Gripper jammed.
56	Measuring motor timeout.		• Measuring motor or sensor malfunction. • Measure head jammed.
57	Nozzle motor timeout.		• Nozzle motor or sensor malfunction. • Nozzle jammed.
58	(Number not assigned)		
59	Power supply current trip.		• Check power supply.
60	(Number not assigned)		
61	Unknown status in protocol routine.		If this error occurs repeatedly, contact local service engineer.
62	No host response after sending request.		• Check protocol settings. • Check LIMS settings. • Check connection between Inversa and LIMS.
63	Nack received after sending request.		• Check protocol settings. • Check LIMS settings.
64	No host response after sending result.		• Check protocol settings. • Check LIMS settings. • Check connection between Inversa and LIMS.
65	Nack received after sending result.		• Check protocol settings. • Check LIMS settings.
66	Unknown protocol selected.		• Check protocol settings.
67	(Number not assigned)		
68	(Number not assigned)		
69	(Number not assigned)		
70	(Number not assigned)		

71	Unknown status in prime routine.		If this error occurs repeatedly, contact local service engineer.
72	Prime Diluent not allowed. Pipette not empty.		Pipette is filled with a sample. Prime is only allowed when the pipette is empty.
73	Prime Cleaning Solution not allowed. Pipette not empty.		Pipette is filled with a sample. Prime is only allowed when the pipette is empty.
74	Error in prime routine -> aborted.		If this error occurs repeatedly, contact local service engineer.
75	Flash memory erased. Default settings are loaded.	Check settings.	• Flash memory malfunction.
76	Checksum error. Default settings are loaded.	Check settings.	Calculated checksum does not match with the checksum stored in EEPROM. • Flash memory malfunction.
77	(Number not assigned)		
78	DS2401 not detected.		If this error occurs repeatedly, contact local service engineer. • Serial number chip malfunction.
79	Communication error with DS2401.		If this error occurs repeatedly, contact local service engineer. • Serial number chip malfunction.
80	SPI error.		If this error occurs repeatedly, contact local service engineer. • Flash memory malfunction.
81	"Write mode" error.		If this error occurs repeatedly, contact local service engineer. • Flash memory malfunction.
82	"Sector protection" error.		If this error occurs repeatedly, contact local service engineer. • Flash memory malfunction.
83	"Pipette data" write error.		If this error occurs repeatedly, contact local service engineer. • Flash memory malfunction.
84	"Patient data" write error.		If this error occurs repeatedly, contact local service engineer. • Flash memory malfunction.
85	"Patient write/read index" write error.		If this error occurs repeatedly, contact local service engineer. • Flash memory malfunction.

86	"Block erase" error.		If this error occurs repeatedly, contact local service engineer. • Flash memory malfunction.
87	"Pipette data" erase error.		If this error occurs repeatedly, contact local service engineer. • Flash memory malfunction.
88	"Pipette data" corrupt.		If this error occurs repeatedly, contact local service engineer. • Flash memory malfunction.
89	"Settings" write error.		If this error occurs repeatedly, contact local service engineer. • Flash memory malfunction.
90	"Card & Credit data" write error.		If this error occurs repeatedly, contact local service engineer. • Flash memory malfunction.
91	(Number not assigned)		
92	(Number not assigned)		
93	(Number not assigned)		
94	(Number not assigned)		
95	(Number not assigned)		
96	(Number not assigned)		
97	(Number not assigned)		
98	(Number not assigned)		
99	(Number not assigned)		
100	(Number not assigned)		
101	(Number not assigned)		
102	(Number not assigned)		
103	(Number not assigned)		
104	(Number not assigned)		
105	Unknown status in End-of-day-wash routine.		If this error occurs repeatedly, contact local service engineer.
106	(Number not assigned)		
107	(Number not assigned)		
108	Unknown status in pipette test routine.	Reset the instrument	If this error occurs repeatedly, contact local service engineer.

109	Error in pipette test routine -> aborted.		If this error occurs repeatedly, contact local service engineer.
110	(Number not assigned)		
111	"ATR" error.	Remove chip card and retry.	Bad or no communication with card. • Chip card incorrectly inserted. • Wrong type of chip card. • Chip card reader malfunction.
112	"CRC" error.	Remove chip card and retry.	Calculated CRC does not match with CRC stored in chip card memory.
113	"Dealer code" error.	Remove chip card and insert correct card.	Dealer code does not match with dealer code set in instrument.
114	"Card type" error.	Remove chip card and insert correct chip card.	Wrong type of chip card inserted. E.g. credit card inserted instead of service card.
115	Card not original.	Remove chip card.	Inserted chip card is not an original Mechatronics card.
116	"Card memory" error.	Remove chip card.	Updated chip card memory (RMA) does not match with source. Send chip card to dealer for further inspection.
117	"Card copy" error.	Remove chip card.	Inserted chip card is a copy. Original chip card already used to upgrade credits.
118	"Credit maximum" error.	Remove chip card.	It is not allowed to upgrade credits. Maximum of credits has been reached.
119	"D-factor" error.	Remove chip card and change D-factor first.	It is not allowed to upgrade credits. • D-factor must be between 1 and 10.000 when A to E chip card is used. • When Q-card is used D-factor must be 0.
120	"Transfer" error.	Try again or use correct chip card.	Software failed to transfer credits from or to a service card. • Infinite credits can not be transferred. • Only service cards can be used to transfer credits. • Communication error with service card. Try again or use other service card.
121	(Number not assigned)		

122	(Number not assigned)		
123	(Number not assigned)		
124	(Number not assigned)		
125	(Number not assigned)		
126	(Number not assigned)		
127	(Number not assigned)		
128	(Number not assigned)		
129	(Number not assigned)		
130	Internal error		If this error occurs repeatedly, contact local service engineer.
131	Internal error		If this error occurs repeatedly, contact local service engineer.
132	Internal error		If this error occurs repeatedly, contact local service engineer.
133	Internal error		If this error occurs repeatedly, contact local service engineer.
134	Internal error		If this error occurs repeatedly, contact local service engineer.
135	(Number not assigned)		
136	(Number not assigned)		
138	(Number not assigned)		
138	(Number not assigned)		
139	(Number not assigned)		
140	(Number not assigned)		

Appendix - Warning list StaRRsed Inversa

Wrng No.	Description	Action	Remark / Possible cause
200	Warning: No printer.	Check printer.	• Printer malfunction.
201	Warning: Printer cover open.	Close cover.	• Cover open. • Cover sensor malfunction.
202	Warning: Out of paper.	Put in a new paper roll.	• Out of paper. • Paper sensor malfunction.
203	Warning: Temperature problem.	Turn off printer.	Contact local service engineer. • Print head too hot. • Printer malfunction.
204	Warning: Power supply problem.		• Voltages out of range. • Power supply malfunction.
205	Warning: printer buffer full.		If this error occurs repeatedly, contact local service engineer. • Printer too slow.
206	(Number not assigned)		
207	(Number not assigned)		
208	(Number not assigned)		
209	(Number not assigned)		
210	Warning: Not possible to rinse. Needle not in up position.		It is not possible to start rinsing, needle might be in sample tube. • Needle unit malfunction.
211	Warning: Last prime too long ago.	Prime system.	Last prime more than 12 hours ago.
212	Warning: Last sample too long ago.	Start End_of_day wash.	Last sample more than 12 hours ago. Clean system.
213	(Number not assigned)		
214	(Number not assigned)		
215	Low credits.	Upgrade credits.	Warning: less than 5% credits left.
216	(Number not assigned)		
217	(Number not assigned)		
218	(Number not assigned)		

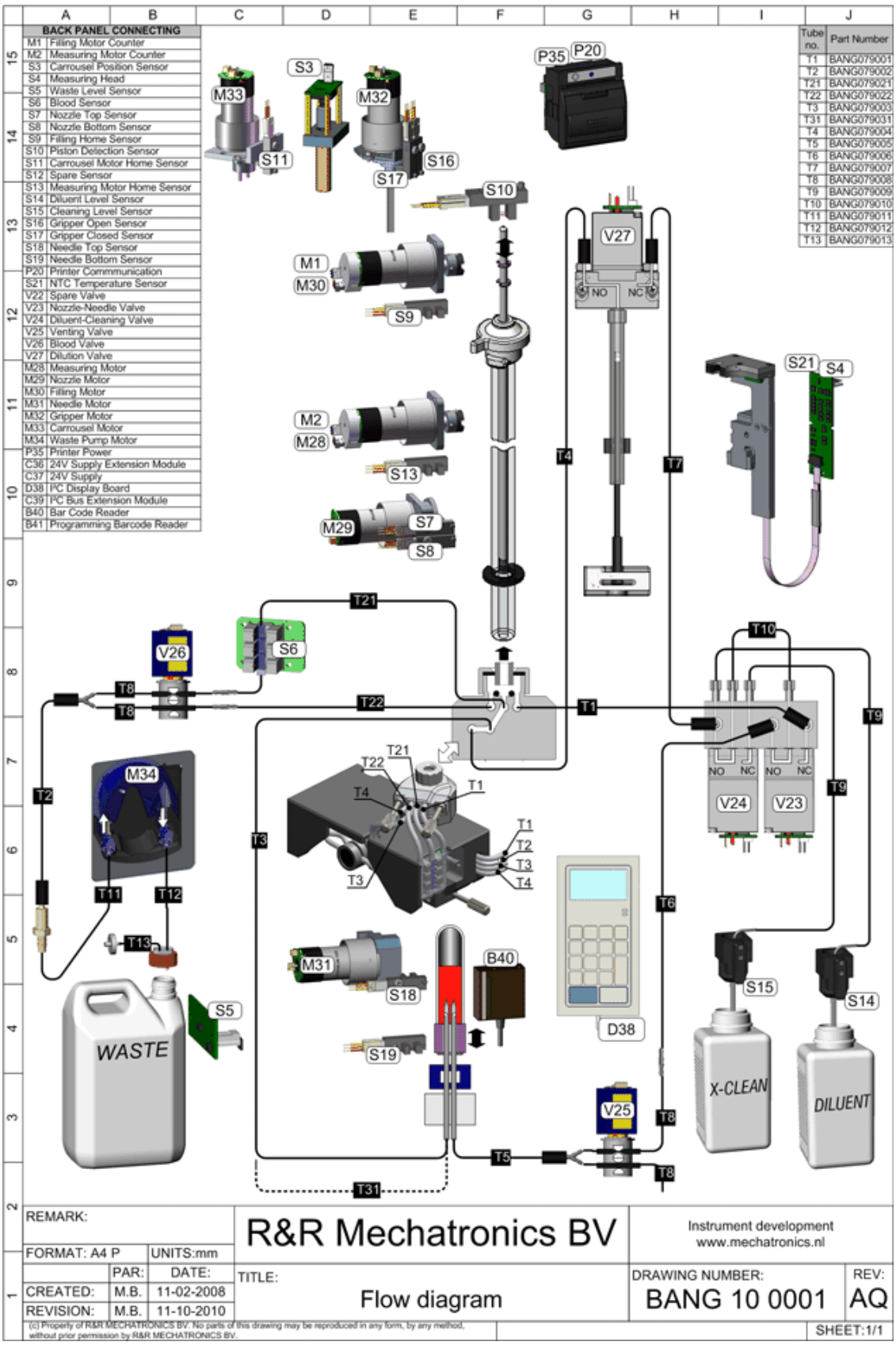
219	(Number not assigned)		

Appendix - Article reference list StaRRsed Inversa

The StaRRsed Inversa is delivered with a complete accessories kit BANG119000. This reference list is for article order numbers only, the actual contents of the accessories kit may be changed without notice.

Part number	Description
BANG010041	Drip plate, basic
BANG020003	Plunger tip
BANG020023	Inversa service tool
BANG029004	Inversa Westergren pipette
BANG030052	Pipette sealing ring
BANG040031	Receiving bin
BANG049002	Needle sealing block
BANG079008	Tube 8
BANG079031	Tube 31 (Only to be used for Citrate Mode)
BANG110141	StaRRsed Inversa 24M User manual
QEDK10002	Euro power cable angular 90º
QEDK130501	Serial Cable SUBD9 male female
QEDV130017	Fuse 1.6 A Slow (220V)
QEDV130019	Fuse 2.5 A Slow (115V)
QEPT080100	Thermal Roll 57 x 47 x 12 mm
QWBM050015	Retaining Washer ∅ 1.5
QWFG010300	Tap for Reagents container
QWLV030901	Teflon tip repair set (1 ring)
QWLV040001	Disc filter 25mm (White) (for waste container)
QWLV050003	O-ring 1.5x1
QWLV050016	O-ring 2.9x1.78
QWLV090008	Tube for peristaltic pump (230VAC)
QRR 010931	Diluent
QRR 010946	X- Clean
BANG31256Q	Mechatronics Instruments Card Q
BANG31256S	Mechatronics Instruments Card S

Appendix - Tube connection StaRRsed Inversa


BACK PANEL CONNECTING
M1 Filling Motor Counter
M2 Measuring Motor Counter
S3 Carrousel Position Sensor
S4 Measuring Head
S5 Waste Level Sensor
S6 Blood Sensor
S7 Nozzle Top Sensor
S8 Nozzle Bottom Sensor
S9 Filling Home Sensor
S10 Piston Detection Sensor
S11 Carrousel Motor Home Sensor
S12 Spare Sensor
S13 Measuring Motor Home Sensor
S14 Diluent Level Sensor
S15 Cleaning Level Sensor
S16 Gripper Open Sensor
S17 Gripper Closed Sensor
S18 Needle Top Sensor
S19 Needle Bottom Sensor
P20 Printer Communication
S21 NTC Temperature Sensor
V22 Spare Valve
V23 Nozzle-Needle Valve
V24 Diluent-Cleaning Valve
V25 Venting Valve
V26 Blood Valve
V27 Dilution Valve
M28 Measuring Motor
M29 Nozzle Motor
M30 Filling Motor
M31 Needle Motor
M32 Gripper Motor
M33 Carrousel Motor
M34 Waste Pump Motor
P35 Printer Power
C36 24V Supply Extension Module
C37 24V Supply
D38 PC Display Board
C39 PC Bus Extension Module
B40 Bar Code Reader
B41 Programming Barcode Reader
Tube no. / Part Number
T1 BANG079001
T2 BANG079002
T21 BANG079021
T22 BANG079022
T3 BANG079003
T31 BANG079031
T4 BANG079004
T5 BANG079005
T6 BANG079006
T7 BANG079007
T8 BANG079008
T9 BANG079009
T10 BANG079010
T11 BANG079011
T12 BANG079012
T13 BANG079013
WASTE
X-CLEAN
DILUENT
NO NC
REMARK:
FORMAT: A4 P
UNITS:mm
PAR:
DATE:
CREATED: M.B. 11-02-2008
REVISION: M.B. 11-10-2010
R&R Mechatronics BV
Instrument development
www.mechatronics.nl
TITLE:
Flow diagram
DRAWING NUMBER:
BANG 10 0001
REV:
AQ
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SHEET:1/1

Appendix - Factory default settings StaRRsed Inversa

Menu text	Setting Menu	Software Default Setting	Factory Setting	Client settings
30 MIN. METHOD	Lab supervisor	OFF	OFF	
EDTA MODE	Lab supervisor	ON	ON	
TEMPERATURE	Lab supervisor	room temperature	room temperature	
Set T.CORR.	Lab supervisor-	ON	ON	
Set DST	Lab supervisor	OFF	OFF	
Set RESULT AT LIMIT	Lab supervisor	ON	ON	
PRINTER (RESULTS)	Lab supervisor	ON	ON	
Set system DATE / TIMET	Lab supervisor	00.00.00	Time	
Set system DATE / TIME	Lab supervisor	01-01-1998	Date	
Select LANGUAGE	Lab supervisor	English	English	
Adjust temp. Sensor	Lab supervisor	18.3	18.3	
ESR TIME (MIN)	Lab supervisor	60 Min	60 Min	
PROTOCOL	Lab supervisor	NO SERIAL OUTPUT	NO SERIAL OUTPUT	
Set BAUDRATE	Lab supervisor	9600	9600	
30 MINUTE OUTPUT	Lab supervisor	OFF	OFF	
CHECKSUM	Lab supervisor	OFF	OFF	
ACK/NACK	Lab supervisor	OFF	OFF	
BARCODE READER	Service	Keyence	Keyence	
MAX.NEEDLE CURRENT	Service	180	180	
SET PISTON POSITION	Service	900	890	

Appendix - Maintenance schedule StaRRsed Inversa

Maintenance schedule StaRRsed Inversa Sample volume <200 Per day Daily Sample volume 150				Daily	Once a week	Level 5	Level 4	Level 3	Level 2	Level 1	Total amount / year
			Clean outside of the aspiration needle	1							
			End-of day-wash procedure / Wash all pipettes	1							
Check			Measure sensor		1						
Check			Check the waste pump tube condition				1				
Check											
Check											
Check											
Based on	750	Fill Nozzle cleaning		every	7	days					
		Clean diluter		every	183	days					
Based on	750	Clean		every	7	days					
Based on	3000	Run fill and clean procedure (X-Clean)		every	28	days					

Appendix - String format for StaRRsed

ESR string format for StaRRsed 60 minutes format

```
[stx]PPPPPPPPPP www WWW AAAAAAAAmm ppp TTT CC EEEEEEEEEEEEEEEEEEEE MMMMMMMMMM[cr][lf][eot]
```

stx	80 data characters	cr	lf	eot			Checksum - OFF	60 min
stx	80 data characters	cr	lf	etx	cs	eot	Checksum - ON	60 min

Data consists, if 30 min. output is switched to OFF				
Position		Description	Format	
1	10	Patient identification text	Text	PPPPPPPPPP
13	15	E.S.R. in mm. 60 minute	xxx	www
18	20	E.S.R. in mm. (60 min corrected for temp)	xxx	WWW
22	30	Aspect	Text	AAAAAAAAA
31	32	Manually added code	xx	mm
34	36	Pipette number	xxx	ppp
39	41	Sedimentation time	xxx	TTT
45	46	Temperature in degree. (Default C.)	xx	CC
48	69	Error messages	Text	EEEEEEEEEEEEEEEEEEEE
71	80	EDTA message	Text	MMMMMMMMMM

CS =1 byte checksum = 256 - (modulo 256 (ASCII string sum)).
ASCII string sum = the ASCII sum of all preceding characters incl. stx, cr, lf and ext modulo 256 (ASCII string sum) = the remainder of the ASCII string sum when divided by 256..

ESR string format for StaRRsed 30 minutes format

```
[stx]PPPPPPPPPP hhh www WWW AAAAAAAAAmm ppp TTT CC EEEEEEEEEEEEEEEEEEEE MMMMMMMMMM[cr][lf][eot]
```

stx	80 data characters	cr	lf	eot			Checksum - OFF	30 min
stx	80 data characters	cr	lf	etx	cs	eot	Checksum - ON	30 min

Data consists, if 30 min. output is switched to ON

Position		Description	Format	
1	10	Patient identification text	Text	PPPPPPPPPP
12	14	E.S.R. in mm. Half hour method	xxx	hhh
16	18	E.S.R. in mm. (calculated to 60 minutes)	xxx	www
20	22	E.S.R. in mm. (60 min corrected for temp)	xxx	WWW
24	32	Aspect	Text	AAAAAAAAA
33	34	Manually added code	xx	mm
37	39	Pipette number	xxx	ppp
41	43	Sedimentation time	xxx	TTT
45	46	Temperature in degree. (Default C.)	xx	CC
48	69	Error messages	Text	EEEEEEEEEEEEEEEEEEEE
71	80	EDTA message	Text	MMMMMMMMMM

Where	ASCII	HEX	DEC
STX	ASCII	$02	02
ETX	ASCII	$03	03

EOT	ASCII	$04	04
LF	ASCII	$0A	10
CR	ASCII	$0D	13
CS	1 byte		

Text.: left aligned followed by spaces (ASCII $20).
xx….: number made up of (xx...) digits 0 9 (ASCIII $30 $39) with leading zeros.
Leading zeros and non-specified positions are filled with spaces (ASCII $20).

Appendix - Protocol Compact bi-directional

Bidirectional protocol definition of the sample request string from the StaRRsed Inversa to the Host computer Positions in the string.

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

ESR Sample request string definition from StaRRsed Inversa to host computer.

STX	**SP**	**E**	**S**	**R**	**S**	**R**	**SP**	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	**SP**	**R**	**SP**	**cs**	**ETX**

Definition of the string:

STX and ETX are at fixed position, first (1) and last (31th) position respectively.

SP	Space character ($20)
E	Capital letter E
S	Capital letter S
R	Capital letter R
1…18	Position of the sample identification (left adjusted) and filled up with spaces at the end of the string
cs	Checksum, one char ($00 .. $FF) that is the EXOR sum of all the data. Data = The position from position 2 up to and including position 29. Take position 2 and position 3 and EXOR those 2. Take the result and EXOR this with position 3 ect till the position 29.
R	At position 28, means that this is the Request string
STX	Char $02
ETX	Char $03

Sample conformation string definition, replied by the host computer to perform an ESR test.

STX	SP	E	S	R	S	R	SP	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	SP	**Y**	SP	cs	ETX

Y = Capital Y at position 28 of the string.

Sample refuse string definition, replied by the host computer to skip the ESR test.

STX	SP	E	S	R	S	R	SP	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	SP	**N**	SP	cs	ETX

N = Capital N at position 28 of the string.

If either the host computer as well the StaRRsed Inversa receives a string it should reply by sending an Acknowledge (char $06) if the string is found okay.
If either the host computer as well the StaRRsed Inversa receives a string it should reply by sending a Non Acknowledge (char $15) if the string is found faulty.

Sample request:

Checksum = always ON

After sending the request string, the StaRRsed Inversa expects a ACK/NACK (seeCompact bi-directional protocol definition) from the Host-computer:

- If the StaRRsed Inversa receives an ACK it will wait for the conformation string and respond with a ACK/NACK according to the protocol definition.
  - When the conformation string is received it will:
    Respond with an ACK if the conformation string is OK and goes to the next sample.

  - Or -

- When the string is not OK it is responding with an NACK and the Host-computer must send the conformation string again.
  After 3 attempts the Host-computer must stop sending the conformation string and the StaRRsed Inversa won't do an ESR on this sample and goes to the next sample.
  The Host-computer needs to be ready for the request string of the next sample!

- If the StaRRsed Inversa does not receive the conformation string within 10 seconds it will send the request string again. After 3 attempts it won't do an ESR on this sample and goes to the next sample.
- If the StaRRsed Inversa receives a NACK it will send the request string again.
  After 3 attempts it will stop communication and generate an error.
- If the StaRRsed Inversa does not get any response, (timeout 10 sec.) it will send the request string again.
  After 3 attempts it will stop communication and generate an error.

Request string example:

Sample ID = 123456789
Request string = ..ESRSR.123456789.....R...(31 bytes)

Sample result:

- Checksum ON/OFF = user defined
- 30 minute output ON/OFF = user defined

The sample result will be output according to the standard Compact/StaRRsed ESR string (See String format for StaRRsed) . If the host computer receives the result string it should reply by sending an ACK or a NACK:

- If the StaRRsed Inversa receives an ACK it will start sending the next result.
- If the StaRRsed Inversa receives a NACK it will send the result string again.
  After 3 attempts it will start sending the next result.
- If the StaRRsed Inversa does not get any response from the host, (timeout 10 sec) it will send the result string again.
  After 3 attempts it will stop communication and generate an error.

Appendix - Protocol MECHATRONICS-01 bidirectional

MECHATRONICS_01 request / workorder record

1	2..126	127	128
STX	Data (125 characters)	**CS**	**ETX**

Position	Data field	# of Bytes	Format	Comment
1	Start of text	1	[STX]	
2	Text distinction code	8	"ESRSR"	Left aligned followed by spaces
10	Instrument ID	20	text	If applicable
30	Sample ID	40	text	
70	Reserved (spaces)	55	text	
125	Request / workorder	1	text	**"R"** = Request; **"Y"** = ESR yes; **"N"** = ESR no
126	Space	1	text	
127	Checksum	1	[CS]	See section Checksum calculation
128	End of text	1	[ETX]	
	Total	**128**		

Text.: left aligned followed by spaces

xx.…: number (digits 0-9) with leading spaces

Non-specified positions are filled with spaces

Request record from analyzer to LIMS: Request (capital R on position 125)

STX	Data	**"R"**	space	CS	ETX

Workorder record from LIMS to analyzer: ESR = Yes (capital Y on position 125)

STX	Data	**"Y"**	space	CS	ETX

ESR = No (capital N on position 125)

STX	Data	**"N"**	space	CS	ETX

MECHATRONICS result record

1	2..254	255	256
STX	Data (253 characters)	**CS**	**ETX**

Position	Data field	# of Bytes	Format	Comment
1	Start of text	1	[STX]	
2	Text distinction code	8	"ESRRE"	Left aligned followed by spaces
10	Instrument ID	20	text	If applicable
30	Sample ID	40	text	
70	Reserved (spaces)	15	text	
85	Aspiration date	10	ddmmyyyy	Text format. E.g. 01012010 = January 1, 2010

95	Aspiration time	5	hhmm	Text format. E.g. 0001 = 0:01 (24-hour clock)
100	ESR 30 minutes (mm/½h)	5	xxxxx	
105	E.S.R. in mm. 60 minute (mm/h)	5	xxxxx	
110	ESR 60 minutes temperature corrected (mm/h)	5	xxxxx	
115	ESR 120 minutes (mm/h)	5	xxxxx	If applicable
120	Reserved (spaces)	10	text	
130	Sample code	5	xxxxx	See section Sample codes
135	Aspect code	5	xxxxx	See section Aspect codes
140	Manually added code	5	xxxxx	
145	Pipette numberPipette number	5	xxxxx	
150	Sedimentation time (minutes)	5	xxxxx	
155	Temperature	5	xxxxx	
160	Dilution rate (%)	5	xxxxx	
165	Column height (mm)	5	xxxxx	
170	Error code	5	xxxxx	See section ESR error codes
175	Limit error message (results)	30	text	See section Limit error message
205	Reserved (spaces)	50	text	
255	Checksum	1	[CS]	See section Checksum calculation
256	End of text	1	[ETX]	
	Total	**256**		

Text.:	left aligned followed by spaces
xx.…:	number (digits 0-9) with leading spaces
	Non-specified positions are filled with spaces

Sample type	Transmitted code
Patient sample	0
QC normal	1
QC abnormal	2

Note: Transmission of QC codes 1 and 2 is part of an internal QC procedure which is still under development. Until this procedure is introduced, all samples are treated as Patient sample (code 0).

Aspect	Transmitted code
Clear	0
Hazy < 10	1
Hazy < 25	2
Hazy > 25	3

ESR error	Transmitted code	Comment
No ERROR	0	
No cells/plasma found	1	ERROR, no result transmitted!
ESR Probably > 140 mm	2	ERROR, no result transmitted!
Too many borders found	3	ERROR, no result transmitted!
Column height	4	WARNING!
Measure error	5	WARNING!
Bubbles on top	6	WARNING!

Limit error	7	ERROR, see Limit error message

Note: See analyzer manual for more information about limit error settings!

When a limit error occurs, the fields for *ESR 30 min, ESR 60 min, temperature corrected ESR* and *ESR 120 min* are filled with spaces and thus results are not send to LIMS.

Together with the other data fields, e.g. the sedimentation time, the operator can see what caused the error and may or may not use the ESR values which are preserved in the limit error message.

Description of the limit error message: **L_err(hhh www ttt ccc ddd)**

- **L_err** means "limit error"
- **hhh** is the 30 minutes ESR
- **www** is the 60 minute ESR
- **ttt** is the temperature corrected 60 minute ESR
- **ccc** is the column height
- **ddd** is the 120 minute ESR (if applicable)

Example of a limit error message without 30 minute ESR and 120 minute ESR:
L_err(--- 123 89 200 ---)

Appendix - Protocol MECHATRONICS-02 unidirectional

1	2..254	255	256
STX	Data (253 characters)	**CS**	**ETX**

Position	Data field	# of Bytes	Format	Comment
1	Start of text	1	[STX]	
2	Text distinction code	8	"ESRRE"	Left aligned followed by spaces
10	Instrument ID	20	text	If applicable
30	Sample ID	40	text	
70	Reserved (spaces)	15	text	
85	Aspiration date	10	ddmmyyyy	Text format. E.g. 01012010 = January 1, 2010
95	Aspiration time	5	hhmm	Text format. E.g. 0001 = 0:01 (24-hour clock)
100	ESR 30 minutes (mm/½h)	5	xxxxx	
105	E.S.R. in mm. 60 minute (mm/h)	5	xxxxx	
110	ESR 60 minutes temperature corrected (mm/h)	5	xxxxx	
115	ESR 120 minutes (mm/h)	5	xxxxx	If applicable
120	Reserved (spaces)	10	text	
130	Sample code	5	xxxxx	See section Sample codes
135	Aspect code	5	xxxxx	See section Aspect codes

140	Manually added code	5	xxxxx	
145	Pipette numberPipette number	5	xxxxx	
150	Sedimentation time (minutes)	5	xxxxx	
155	Temperature	5	xxxxx	
160	Dilution rate (%)	5	xxxxx	
165	Column height (mm)	5	xxxxx	
170	Error code	5	xxxxx	See section ESR error codes
175	Limit error message (results)	30	text	See section Limit error message
205	Reserved (spaces)	50	text	
255	Checksum	1	[CS]	See section Checksum calculation
256	End of text	1	[ETX]	
	Total	**256**		

Text.: left aligned followed by spaces

xx.…: number (digits 0-9) with leading spaces

Non-specified positions are filled with spaces

Sample type	Transmitted code
Patient sample	0
QC normal	1
QC abnormal	2

Note: Transmission of QC codes 1 and 2 is part of an internal QC procedure which is still under development. Until this procedure is introduced, all samples are treated as Patient sample (code 0).

Aspect	Transmitted code
Clear	0
Hazy < 10	1
Hazy < 25	2
Hazy > 25	3

ESR error	Transmitted code	Comment
No ERROR	0	
No cells/plasma found	1	ERROR, no result transmitted!
ESR Probably > 140 mm	2	ERROR, no result transmitted!
Too many borders found	3	ERROR, no result transmitted!
Column height	4	WARNING!
Measure error	5	WARNING!
Bubbles on top	6	WARNING!

Limit error	7	ERROR, see Limit error message

Note: See analyzer manual for more information about limit error settings!

When a limit error occurs, the fields for *ESR 30 min, ESR 60 min, temperature corrected ESR* and *ESR 120 min* are filled with spaces and thus results are not send to LIMS.

Together with the other data fields, e.g. the sedimentation time, the operator can see what caused the error and may or may not use the ESR values which are preserved in the limit error message.

Description of the limit error message: **L_err(hhh www ttt ccc ddd)**

- **L_err** means "limit error"
- **hhh** is the 30 minutes ESR
- **www** is the 60 minute ESR
- **ttt** is the temperature corrected 60 minute ESR
- **ccc** is the column height
- **ddd** is the 120 minute ESR (if applicable)

Example of a limit error message without 30 minute ESR and 120 minute ESR:
L_err(--- 123 89 200 ---)

CS = Checksum, XOR sum off all the data (with the exception of CS, STX, and ETX).
E.g.: CS = ((byte2 XOR byte3) XOR byte 4) XOR….etc.

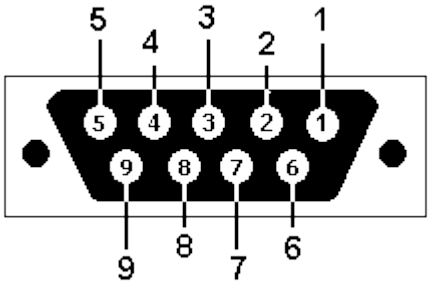
Note: Cannot be equal to that of the ETX byte (03h).

The CS byte verifies the accuracy of each transmitted message. Before transmission, the value of the CS byte is calculated by the “exclusive-or’ing” of all data bytes in the message, with the exception of CS, STX, and ETX. Since the CS byte precedes the ETX byte within the data stream, the calculated value for CS cannot be equal to that of the ETX byte (03h). Therefore, if the calculated CS value is 03h, the transmitted CS byte is set to the substitute value 83h in order to avoid erroneous action by the receiving device.

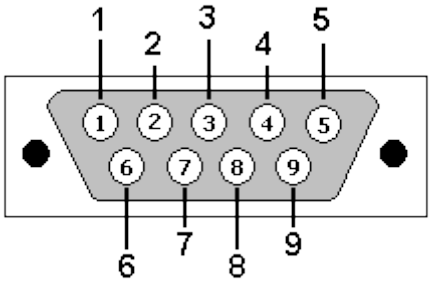
Appendix - RS-232 (DB9 pins female) hardware back panel connector

The 9-pins sub D (female) connector is for the serial output of the StaRRsed Inversa.

Connector layout DB9



DB9: View looking into female connector



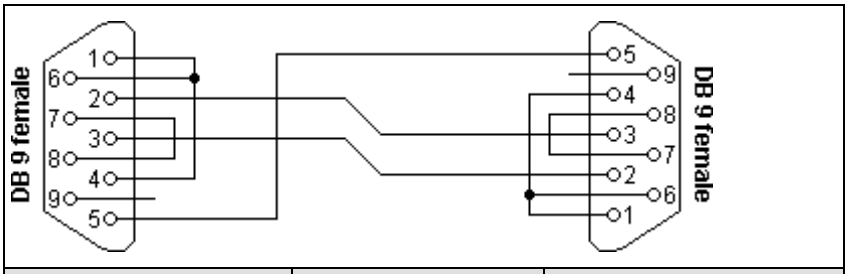
DB9: View looking into male connector

Pin no	Name	Dir	Notes / Description
1	DCD	Input	Data Carrier Detect. Raised by DCE when modem synchronized.
2	RD (RXD)	Input	Receive Data (a.k.a RxD, Rx). Arriving data from DCE.
3	SD (TXD)	Output	Transmit Data (a.k.a TxD, Tx). Sending data from DTE.
4	DTR	Output	Data Terminal Ready. Raised by DTE when powered on. In auto-answer mode raised only when RI arrives from DCE
5	GND (SG)		ground
6	DSR	Input	Data Set Ready. Raised by DCE to indicate ready.
7	RS (RTS)	Output	Request To Send. Raised by DTE when it wishes to send. Expects CTS from DCE.
8	CS (CTS)	Input	Clear To Send. Raised by DCE in response to RTS from DTE
9	RI	Input	Ring Indicator. Set when incoming ring detected - used for auto-answer application. DTE raised DTR to answer.

Null modem with loop back handshaking for DB 9 connectors

The simple null modem cable without handshaking shows incompatibilities with common software. The main problem with this cable is that there is a possibility for the software to hang if it checks the modem signal lines in a proper way. I.e. with this null modem cable, good written programs will perform worse than badly written programs.

To overcome this problem and still be able to use a cheap null modem communication cable with only three lines in it, a fake null modem cable layout has been defined. The null modem cable with loop back handshaking resulted from this.



Connector 1	Connector 2	Function
2		RD (RXD) <- SD (TXD)
3		SD (TXD) -> RD (RXD)
5		GND (SG)
1 + 4 + 6		DTR -> CD + DSR
	1 + 4 + 6	DTR -> CD + DSR
7 + 8		RS (RTS) -> CS (CTS)
	7 + 8	RS (RTS) -> CS (CTS)

The main purpose of this null modem cable is to let well defined software think there is handshaking available, with a null modem cable which has no provisions for it.

All specified RS232 signals are completely isolated from the 'computer earth' and the 'mains supply'.

Handshake:

Hardware handshake is not applied.

Change the data transmission parameters:
From the transmission parameters, only the baud rate can be selected from 1200 up to 9600.

Appendix - Configuration barcode readers

The Barcode interface can handle two types of barcode readers,

- The Opticon (6 mil resolution).
- The Keyence (4 mil resolution).

If you are using labels with a higher density, contact your local distributor or agent.

The Barcode reader may be set to accept check digits, however this needs to be programmed by the distributor. Coda bar, Code 39, Code128, UPC, EAN and ITF 2 or 5 barcode types can be read with those barcode reader types.

To set-up the barcode readers to client specifications, use the set-up tools for the barcode readers. Detailed information can be found in Keyence Configuration manual MRN-011 or in Opticon Configuration manual MRN-015.

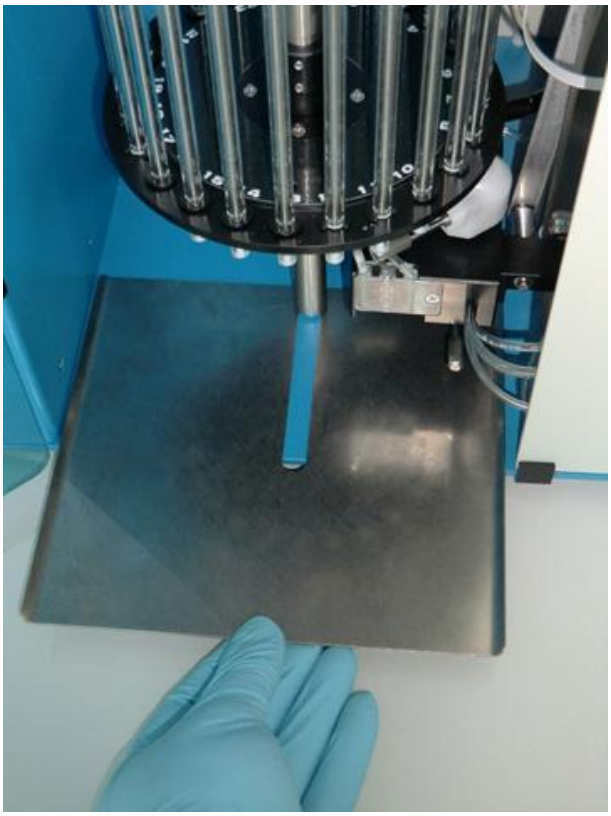
18. WORK INSTRUCTION STARRSED INVERSA

Work instruction section

Work instruction Number 400	
Page 1 of 1	**Purpose:**: Daily maintenance
Safety: *Bio Hazard area*	
Instrument: StaRRsed Inversa	**Revision:** Draft, September 2010

Prepare disinfectant: (if not already prepared) **(180).**
Add **10 ml** bleach (sodium hypochlorite) to **190 ml** de-ionized water. **(5% solution)**
This disinfectant is for cleaning of all external parts that are exposed to blood.

1. Wipe the lower tube holder of the needle unit.
2. Wipe the stainless steel drip plates below the pipette carousel and needle unit.



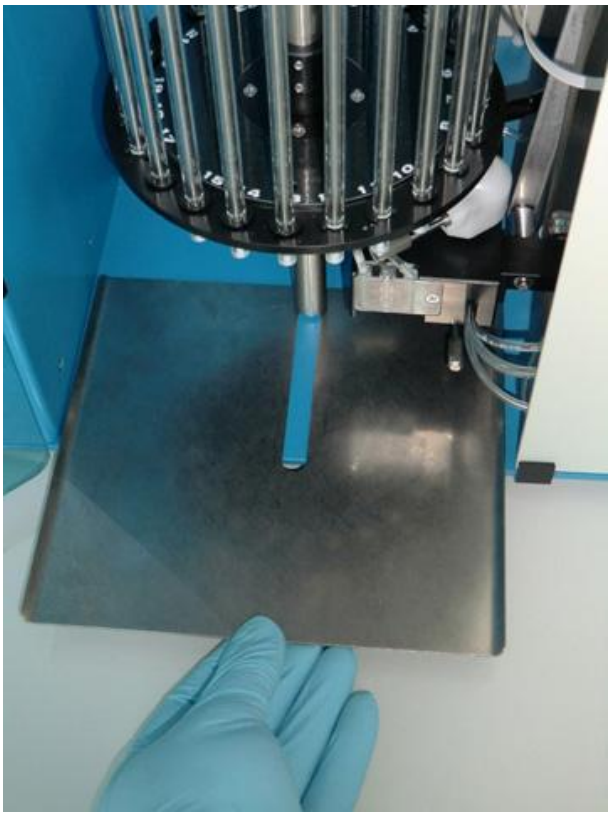
3. In the Main menu use the function [END_OF_DAY WASH] .
4. Check the system for leakage.

Work instruction Number 401	
Page 1 of 6	**Purpose:**Weekly maintenance
Safety: *Bio Hazard area*	
Instrument: Inversa	**Revision:** Draft, September 2010

NOTE: Chip card type **S** is required !

Prepare disinfectant: (if not already prepared) **(180).**
Add **10 ml** bleach (sodium hypochlorite) to **190 ml** de-ionized water. **(5% solution)**
This disinfectant is for cleaning of all external parts that are exposed to blood.

1. Wipe the lower tube holder of the needle unit.
2. Wipe the stainless steel drip plates below the pipette carousel and needle unit.



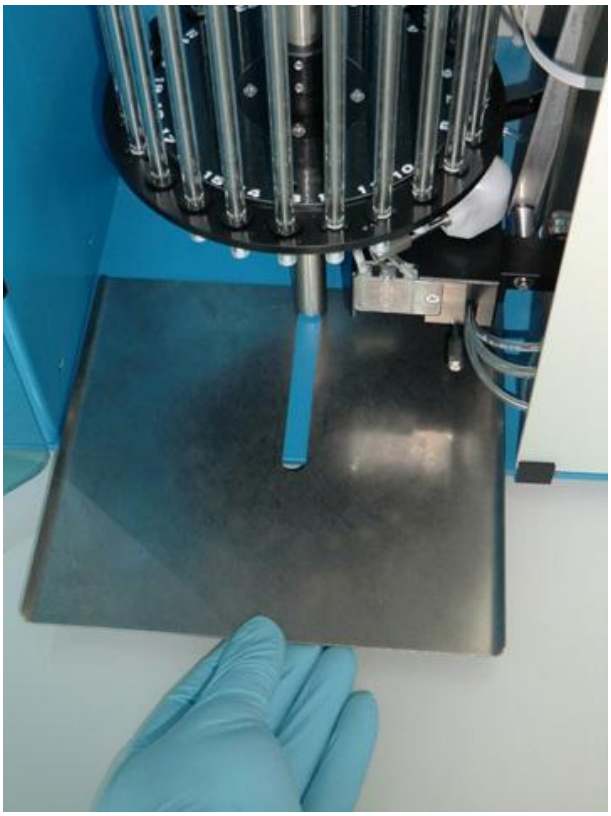
3. In the Main menu use the function [END_OF_DAY WASH] .
4. Check the system for leakage.
5. Inspect sample needle condition:
   Menu SERVICE - MOTOR CONTROL - NEEDLE M31. Press **[ARROW DOWN]** twice to expose the needle tips. If the tips are worn, replace the needle.

Work instruction Number 402	
Page 1 of 1	**Purpose:**: Level 2 maintenance
Safety: *Bio Hazard area*	
Instrument: StaRRsed Inversa	**Revision:**: Draft, September 2010

NOTE: Chip card type **S** is required !

Prepare disinfectant: (if not already prepared) **(180).**
Add **10 ml** bleach (sodium hypochlorite) to **190 ml** de-ionized water. **(5% solution)**
This disinfectant is for cleaning of all external parts that are exposed to blood.

1. Wipe the lower tube holder of the needle unit.
2. Wipe the stainless steel drip plates below the pipette carousel and needle unit.



3. In the Main menu use the function [END_OF_DAY WASH] .
4. Check the system for leakage.
5. Inspect sample needle condition:
   Menu SERVICE - MOTOR CONTROL - NEEDLE M31. Press **[ARROW DOWN]** twice to expose the needle tip. If the tips are worn, replace the needle assembly.

6. Check the waste pump tube condition. Replace the tube if it appears worn or leaking:

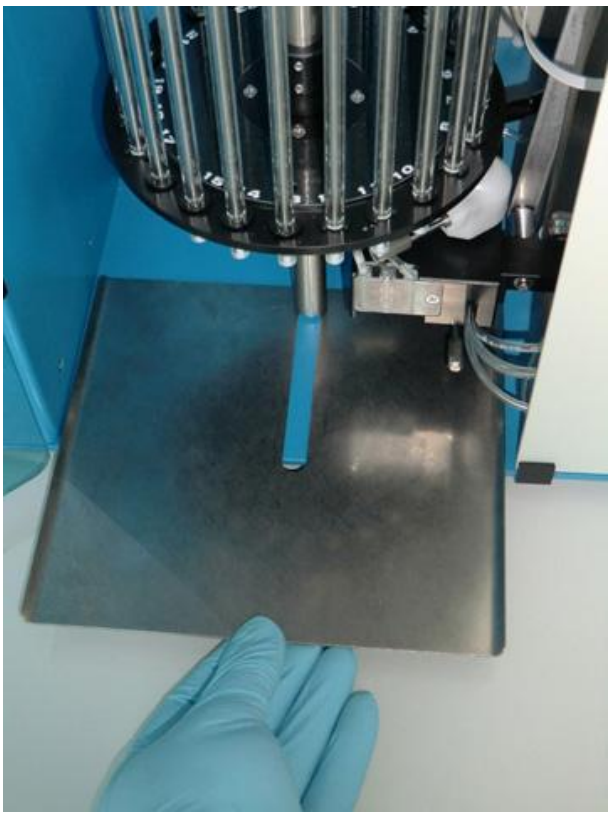
18.1. WI-403 Level 3 maintenance

Work instruction Number 403	
Page 1 of 1	**Purpose:**: Level 3 maintenance
Safety: *Bio Hazard area*	
Instrument: StaRRsed Inversa	**Revision:**: Draft, September 2010

NOTE: Chip card type **S** is required !

Prepare disinfectant: (if not already prepared) **(180).**
Add **10 ml** bleach (sodium hypochlorite) to **190 ml** de-ionized water. **(5% solution)**
This disinfectant is for cleaning of all external parts that are exposed to blood.

1. Wipe the lower tube holder of the needle unit.
2. Wipe the stainless steel drip plates below the pipette carousel and needle unit.



3. In the Main menu use the function [END_OF_DAY WASH] .
4. Check the system for leakage.

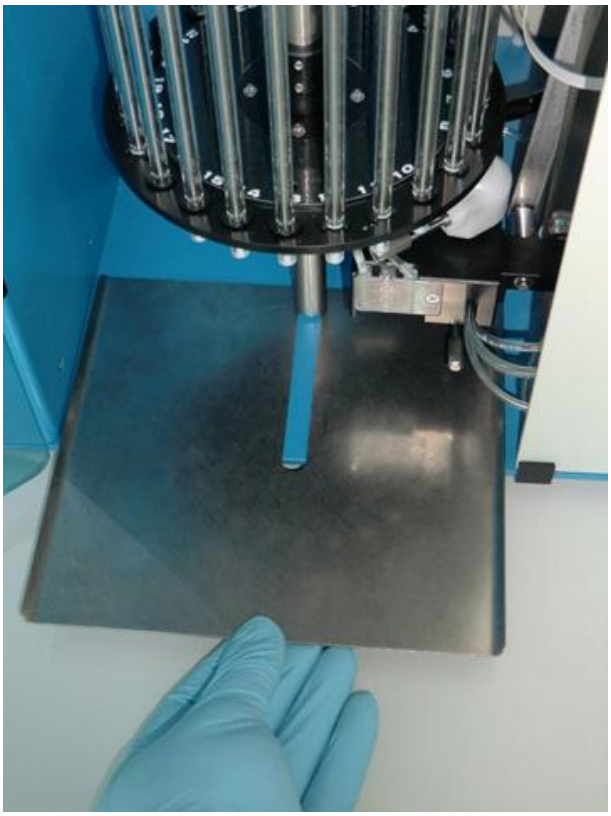
5. Inspect sample needle condition:
   Menu SERVICE - MOTOR CONTROL - NEEDLE M31. Press **[ARROW DOWN]** twice to expose the needle tip. If the tips are worn, replace the needle assembly.
6. Check the waste pump tube condition. Replace the tube if it appears worn or leaking:

Work instruction Number 404	
Page 1 of 1	**Purpose:**: Level 4 maintenance
Safety: *Bio Hazard area*	
Instrument: StaRRsed Inversa	**Revision:**: Draft, September 2010

NOTE: Chip card type **S** is required !

Prepare disinfectant: (if not already prepared) **(180).**
Add **10 ml** bleach (sodium hypochlorite) to **190 ml** de-ionized water. **(5% solution)**
This disinfectant is for cleaning of all external parts that are exposed to blood.

1. Wipe the lower tube holder of the needle unit.
2. Wipe the stainless steel drip plates below the pipette carousel and needle unit.



3. In the Main menu use the function [END_OF_DAY WASH] .
4. Check the system for leakage.
5. Inspect sample needle condition:
   Menu SERVICE - MOTOR CONTROL - NEEDLE M31. Press **[ARROW DOWN]** twice to expose the needle tip. If the tips are worn, replace the needle assembly.

6. Check the waste pump tube condition. Replace the tube if it appears worn or leaking:

19. GLOSSARY OF TERMS

B

19.1.1.1.1. Bidirectional

Bidirectional communication means that there is two-way communication from the StaRRsed Inversa to the HOST (sample requests and results) and from the HOST to the StaRRsed Inversa (confirmation or denial of sample requests).

C

19.1.1.1.2. Citrate mode

Citrate mode is used for *pre-diluted samples* collected in tubes with *sodium citrate anticoagulant-diluent*. The samples are *not* diluted on the StaRRsed Inversa during aspiration.
The concentration of sodium citrate within the diluent solution in the tube should be 3.2%. This is not to be confused with the required dilution rate of blood and diluent.
For example, in a citrate tube with a total draw volume of 1.6 ml (= 5 volumes), the amount of pre-filled diluent must be 0.32 ml (= 1 volume). If this information is not provided by the tube manufacturer, it should be checked by the customer.

E

19.1.1.1.3. EDTA mode

EDTA mode is used for *undiluted samples* collected in tubes with *EDTA anticoagulant*. The samples are automatically diluted on the StaRRsed Inversa during aspiration.
The usual amount of EDTA in sample tubes is 1.8 mg per 1 ml blood. 1 ml of blood weighs ca. 1060 mg and the concentration of EDTA is therefore 0.17% and well within the requirements for the EDTA mode on this instrument.

19.1.1.1.4. ESR

ESR is short for **Erythrocyte Sedimentation Rate.** It is the amount of sedimentation (setting) of erythrocytes (red blood cells) in a blood column during a specified time.

H

19.1.1.1.5. Hazy

A sedimentation is reported to be "**hazy**", when the boundary between blood plasma and erythrocytes can not be defined clearly.

19.1.1.1.6. Host

In this manual, the term **HOST** is used to indicate the computer system and associated software (LIMS) that provides the sample management for the laboratory.

I

19.1.1.1.7. IVD

IVD is short for **In Vitro Diagnostic.** This kind of diagnostic is performed on biological samples in a test tube, or more generally in a controlled environment outside a living organism. *In vitro* means *in glass* in Latin.

M

19.1.1.1.8. MRN

MRN is short for **Master Registration Number**. It is used as an identification number for any manual for Mechatronics products.

T

19.1.1.1.9. Temperature correction

The sedimentation of blood cells is a temperature dependent process. To achieve comparable results, **temperature correction** should always be used. The ESR results are then corrected to the value they would have been at the *standard temperature of 18.3°C*.

U

19.1.1.1.10. Unidirectional

Unidirectional communication means that there is only one-way communication from the StaRRsed Inversa to the HOST. Only sample results and result related messages are send.

W

19.1.1.1.11. WI

WI is short for **Work Instruction** and is used with an index number for a range of work instructions.

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